

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

SECURITY NATIONAL BANK, as
Conservator for JMK, a minor child,

No. C11-4017-MWB

Plaintiff,

Sioux City, Iowa

vs.

January 6, 2014

8:03 a.m.

ABBOTT LABORATORIES,

Volume 1 of 10

Defendant.

/

REDACTED TRANSCRIPT OF TRIAL
BEFORE THE HONORABLE MARK W. BENNETT
UNITED STATES DISTRICT JUDGE, and a jury.

APPEARANCES:

For the Plaintiff:

AMANDA BRANDY VAN WYHE, ESQ.
 TIMOTHY S. BOTTARO, ESQ.
 Vriezelaar, Tigges, Edgington,
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STEPHEN C. RATHKE, ESQ.
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For the Defendant:

JOHN C. GRAY, ESQ.
 Heidman Law Firm
 1128 Historic 4th Street
 Sioux City, IA 51102

DANIEL E. REIDY, ESQ.
 JUNE K. GHEZZI, ESQ.
 GABRIEL H. SCANNAPIECO, ESQ.
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 Jones Day
 Suite 3500
 77 West Wacker Drive
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Also present:

Louise Deitloff
 Daniel Morrison

Court Reporter:

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 Sioux City, IA 51101
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1 (Proceedings convened outside the presence of the jury
2 venire.)

3 THE COURT: Okay. Well, we're getting started late,
4 but we need to get started, so I have a couple of things I need
5 to take up, but I was just advised by Mr. King that he believes
6 there's a problem in the verdict form, so it's a little bit late
7 to be raising it, but let's -- let's hear what the problem is.

8 MR. KING: Your Honor --

9 THE COURT: You'll have to turn your microphones on.

10 MR. KING: I'm new at this. I'll come up. Your
11 Honor, I was observing that the verdict form would call for the
12 jury to pass on the plaintiff's theories of design and warning.
13 Integral to those theories are issues that go to state of the
14 art. And so the jury theoretically could find for the plaintiff
15 on design and answer yes to the state of the art which would be
16 irreconcilable in my view.

17 And I would suggest to the Court that a separate
18 question on the verdict on state of the art is not necessary
19 because the defense is available and can be argued in defense of
20 the design and the warning claims.

21 For example, design and warning each call for
22 reasonable safe alternatives, practical results that are
23 available. But that's integral to the state of the art defense.
24 So I'm just concerned that we have the potential for an
25 irreconcilable verdict.

1 THE COURT: What's the -- who's going to be responding
2 for the defense?

3 MR. REIDY: Dan Reidy will, Your Honor. Your Honor, I
4 believe that we need a separate part of the jury verdict form
5 that addresses the affirmative defense of state of the art, so I
6 think we need to have that in here.

7 THE COURT: And it seems to me in argument can't the
8 plaintiff just point out that if they award -- can't you just
9 point out what the jury should do to avoid an irreconcilable
10 problem?

11 MR. KING: Certainly we can argue it, but sometimes
12 juries don't understand or don't follow. And so the point is
13 that the verdict form gives the jury the ability to answer
14 questions that are irreconcilable. That's all.

15 THE COURT: Well, I think that's true, but if they
16 answer it that way, it's not irreconcilable. You lose.

17 MR. KING: So the jury could find a design defect
18 claim, for example, and still find that the product was made to
19 the state of the art. I don't understand how that can square
20 given the definition --

21 THE COURT: Well, because I thought we had all agreed
22 that the affirmative defenses were going to be carved out in the
23 verdict form and that I would determine the effect of the
24 verdict form after the verdict. I thought that was the
25 understanding and that's why it was set up this way. Now, maybe

1 I missed something.

2 MR. KING: I'm not speaking to the learned
3 intermediary issue. That stays on the verdict form pursuant to
4 your rulings. But I know that our initial submission on our
5 verdict did not carve out the state of the art defense. And
6 it's just my experience that you don't have a separate question
7 on that because of this danger. That's all. But we can
8 certainly argue it and hope for the best.

9 THE COURT: Well -- so yeah, I think you make a good
10 point here. So why do we need it for state of the art?

11 MR. REIDY: Judge, I think that the statutory Iowa
12 defense of state of the art, that we are entitled to have the
13 jury consider that as an affirmative defense. And in order to
14 have that reflected on the verdict form, we need it separately
15 addressed on the verdict form. We can't have it built into
16 whether or not they prove their elements of their claim and then
17 not have the jury addressed -- it's instructed on.

18 THE COURT: Well, it's instructed on it.

19 MR. REIDY: Yeah, but --

20 THE COURT: But there's not a verdict form --
21 well . . .

22 MR. REIDY: There's essentially, Judge -- on each of
23 the claims, there's a part of the verdict form that addresses
24 each of those, and on each of the affirmative defenses there's a
25 part of the jury verdict form that addresses those. That was

1 the symmetry that I think we agreed upon with the Court to begin
2 with, and I think it's one that we have to have. We have to
3 have --

4 THE COURT: Well, you don't have to have it in the
5 verdict form. You have to have it in the instruction.

6 MR. REIDY: Yes, although I think --

7 THE COURT: You cite me a case that says you have to
8 have it in the verdict form. You don't even have to have a
9 specific verdict form. I could use a general verdict. Do you
10 find for the plaintiff? If so, how much? I could. I never do
11 that. But you cite me a single case from any circuit that has
12 ever said you have to have a separate verdict question for every
13 affirmative defense.

14 MR. REIDY: I can't do that as I stand here.

15 THE COURT: Because you know it doesn't exist.

16 MR. REIDY: Well, I don't know actually whether it
17 does or it doesn't.

18 THE COURT: Well, what do you think?

19 MR. REIDY: It may well be that it does not, Judge. I
20 guess what I'm saying is that in order to have the affirmative
21 defense appropriately considered and to reflect that
22 consideration by the jury, we think it's very important that it
23 be separately addressed on the verdict form.

24 THE COURT: Well, that's like saying -- the flip side
25 of that is, to show you how ridiculous your position is, it's

1 like saying for every one of the plaintiff's theories I have to
2 have a special verdict form on each of the elements to make sure
3 that they've considered it so they answer to each element have
4 you considered this, yes or no. Why is that any different?

5 MR. REIDY: I guess, Judge, I think that it's not the
6 same to say that you have to have the verdict form address each
7 element because the elements -- if the Court instructs you have
8 to find all these elements and then on the verdict form they
9 check I find on that claim, then it, of course, is assumed that
10 they found on that element. I think to remove the affirmative
11 defense of state of the art from the verdict form and then -- I
12 mean, I don't think the instructions then even cover it as
13 they're currently there.

14 THE COURT: What do you mean the instructions don't
15 cover it?

16 MR. REIDY: Well, then the Court would have to tell
17 the jury, you know, what the state of the art defense is which
18 it does in its --

19 THE COURT: Well, I do that. I instruct on it.

20 MR. REIDY: Yes, of course. And then I think it would
21 be very difficult to tell them then how to respond to the -- the
22 jury verdict form, you know, where we have affirmative defenses
23 broken out separately. And I think that if we're going to break
24 the affirmative defenses out separately which I think is fully
25 appropriate and which the Court had done in its original verdict

1 form that it makes sense to have each of them there. And we can
2 address that. And if -- I mean, we have time to do this. We
3 can also have the Court address it in an instruction as far as
4 the risk or any risk of inconsistent verdicts.

5 THE COURT: Well, I would certainly have to change on
6 page 31 the language in the instruction, not the definition of
7 the state of the art defense but the effect of the state of the
8 art defense. I'd certainly have to make that change.

9 Mr. Gray, do you have a view on this?

10 MR. GRAY: I do not, Your Honor.

11 THE COURT: Well, I think I'll leave it in. And, you
12 know, it will just be up to the plaintiff to explain it
13 effectively in the closing argument so that there isn't an
14 inconsistency. You know, if it had been raised earlier, I might
15 have done something else, but, you know, I instruct at the
16 beginning, so we've gotta have these ready to go.

17 There are -- with regard to the instructions, we had
18 inadvertently left out my instruction on questions by the jurors
19 because I do allow the jurors to ask questions. I've just been
20 doing that for the last year and a half or so. It's really been
21 great. I'm not sure I've ever actually had an objection by the
22 lawyers to a question. Usually average eight to ten questions a
23 trial. They actually ask some really good questions. The
24 lawyers often at sidebar will say to me, gee, I wish I had
25 thought to ask that.

1 And just so you know, here's how it works. At the end
2 of every witness when the lawyers are done examining, I'll ask
3 the jurors if they have any questions. If they do, they pass
4 them down to the court security officer. They give it to me. I
5 review them, and then I show them to the lawyers up at sidebar.
6 We have a system where all the microphones are shut off. The
7 noise keeps the jurors from hearing what we have to say. And I
8 just have you state an objection. Like I said, I don't think
9 I've ever had one, but if you have an objection, I would just
10 rule on it just like I would any other objection.

11 If I sustain the objection, obviously I'm not going to
12 answer the -- ask the question. If there is an objection and I
13 overrule it, I ask the questions of the witness. But after each
14 question -- let's say there are more than one. Maybe there are
15 three questions. I ask the question of the witness, and then I
16 give the lawyers the opportunity to ask any follow-up questions
17 directly related to that question. And I start with the party
18 that has called the witness. Then I'll ask the next question,
19 give the lawyers an opportunity to ask any follow-up questions.

20 So any other objections or problems with the
21 instructions that you want to make any record on at this time?

22 MR. KING: Your Honor, for the plaintiff, may I speak
23 from here?

24 THE COURT: Absolutely.

25 MR. KING: I think that we're on record on the -- our

1 view that there's not an evidentiary basis to support the
2 learned intermediary defense. And my concern -- I'm aware of
3 your view, and my concern always is unringing the bell. If you
4 should decide at the time of submission that it shouldn't be in,
5 they will have heard it. And I would just renew the objection
6 and point out that we know of no evidentiary basis to support
7 it.

8 THE COURT: Thank you. And if I ultimately conclude
9 it, then I'll just ask the jury to cross it out. But I don't
10 buy the ringing the bell theory, so I don't actually buy it in
11 virtually anything including jury selection and everything else.
12 So your objection's overruled, but I appreciate it.

13 Do you want to also -- are you satisfied that you've
14 made a sufficient objection to the state of the art defense
15 verdict form, or do you want to make any other record on that?

16 MR. KING: It's my view that if you believe there's a
17 basis to submit state of the -- or I'm sorry, state of the art
18 or --

19 THE COURT: I'm back to the original problem you had
20 with the verdict form with regard to state of the art, and I
21 just want to make sure you've had an adequate opportunity to
22 make any record with regard to your objection on that.

23 MR. KING: Well, I trust that we've been on the record
24 all along.

25 THE COURT: Yeah.

1 MR. KING: And, therefore, I'm satisfied that the
2 record is complete.

3 THE COURT: All right. Thank you.

4 MR. KING: Thank you, Your Honor.

5 THE COURT: Which brings me to -- I think you would
6 all be familiar with this rule, but because there are so many
7 lawyers in this case, I don't allow tag team lawyering. You
8 know, it's not the World Federation of Wrestling.

9 So, for example, if Mr. Gray were to blurt out an
10 objection during one of the plaintiff's witnesses, then he's
11 going to be the one doing the cross-examination whether he
12 intended to or not. And the whole point is that, you know, you
13 can't have multiple people making objections. There's one -- I
14 assume you've assigned one lawyer to each witness, so the lawyer
15 that's going to be doing the cross-examination is the one that's
16 going to be doing the objecting. And we're not trading off, in
17 other words, so I think you all -- you all understand what I
18 mean by no tag team lawyering? Yeah. And I'm sure you're all
19 very used to that, so okay.

20 You know, the major thing I haven't ruled on is this
21 motion to seal. Is that going to come up today?

22 MR. REIDY: We do not anticipate it coming up today,
23 Judge.

24 THE COURT: Okay. We are having a hard time
25 finding -- when you filed the motion, you filed an Exhibit B

1 which allegedly said the documents that were subject to it were
2 filed under seal. We can't find them anywhere, so do you have
3 anything that actually lists the -- which exhibits are --

4 MR. REIDY: Let me just check, Judge.

5 THE COURT: Yeah.

6 MR. REIDY: Judge, we can certainly give you a list by
7 tomorrow morning as well as a set if you would like of the
8 Exhibit B documents. I don't think we have them broken up and
9 at hand.

10 THE COURT: When do you think we're going to get to
11 them? Will the plaintiff get to them in their case, or is it
12 going to come up mostly in the defense case?

13 MS. GHEZZI: Well, Your Honor, we don't really know.
14 I think it's probably going to come up --

15 THE COURT: In the plaintiff's case?

16 MS. GHEZZI: Yeah.

17 THE COURT: Yeah.

18 MS. GHEZZI: But I don't anticipate today, but it's
19 hard to say.

20 THE COURT: Okay.

21 MS. GHEZZI: But probably not.

22 THE COURT: Okay. Here's another rule. You either
23 need to wear a lapel mike or speak directly into the microphone
24 because the acoustics are good with the microphones, but it's
25 such a big barn that without the microphone the court reporter

1 and I -- even though you all can hear yourselves, we can't hear
2 you.

3 MS. GHEZZI: Gotcha.

4 THE COURT: So it will be hard to get used to. And
5 it's -- the light means that it's on. And in some courtrooms
6 the default is on and you have to press the little bar. Ours is
7 the opposite.

8 MS. GHEZZI: Okay. Thank you.

9 THE COURT: And if you're having a private
10 conversation with the client, I notice the microphone's on, I'll
11 ask you to shut your microphone off because it's hard to pay --
12 you have so many things to pay attention to, it's hard to
13 so . . .

14 You know, I might have been a little precipitous in
15 my -- I mean, I do have this view that most of the claims of
16 trade secrets really aren't. But I know you have some concerns
17 because you know there's going to be a lawyer from a competitor
18 that may be at the trial.

19 MS. GHEZZI: Well, I know that there is a lawyer from
20 the competitor who has asked me on several occasions when it's
21 going and stating that they'd like to be there as late as
22 Friday. I did not answer that e-mail. But I don't know. I
23 cannot represent to the Court that I know that somebody from the
24 competitor will be here. But I can just say that that's what
25 I've been told.

1 THE COURT: Okay. Let me ask you this. Would it be
2 sufficient do you think -- and please -- you know, you have to
3 protect your client. That's not my job. I'm not looking out
4 for your client's interest, I mean, only as a neutral but not as
5 an advocate.

6 But one of the things I thought of, we could certainly
7 seal any record that you wanted in terms of the court filing and
8 it would be under seal and nobody could go on Pacer and have
9 access to it. Nobody could call the clerk and say, hey, we'll
10 be glad to pay for a copy of that exhibit. And so I'm trying to
11 draw maybe a balance here.

12 But to the extent that witnesses testify about it, I
13 don't mind actually sealing the transcript if you'll tell me
14 when you think it needs to be sealed. We can seal that portion
15 of the transcript so when the case is over and it's on appeal
16 nobody could get access to the transcript. And that would
17 obviate the need of trying to close the courtroom physically and
18 exclude people. But maybe that isn't enough of a protection for
19 you and your client. And you're in a better position to make
20 that judgment really than I am.

21 MS. GHEZZI: You know, Your Honor, I think that as it
22 develops organically we can sort of see. I don't know what
23 they're going to use. And our client is here, and if we see --
24 if I see a lawyer from the competitor that I know, I can point
25 that out. You know, we can do that kind of thing.

1 THE COURT: And generally as you can see, we don't
2 have a huge audience watching our trials.

3 MS. GHEZZI: Yes. I'm blaming that on the weather.

4 THE COURT: Well, blame it on lack of interest or how
5 boring our trials are. I'm kidding. So if you're comfortable
6 kind of playing it by ear, we can do that. You know, I don't
7 want to harm your client with the release of any trade secret.

8 MS. GHEZZI: I understand.

9 THE COURT: But I'm kind of wondering, even if the
10 lawyer's sitting in the office and somebody's talking, how much
11 of it could he actually take down that would -- I don't know.
12 But I'm open to sealing the courtroom if we have to.

13 MS. GHEZZI: Okay.

14 THE COURT: Okay?

15 MS. GHEZZI: Thank you, Judge.

16 THE COURT: Because even though I'm skeptical of trade
17 secret claims, you know, this is a product where I could
18 understand that there would be some legitimate trade secret
19 claims. And I was looking at some documents, but I don't think
20 I looked at the right documents. And then when I went this
21 weekend to look at the documents you identified in Exhibit B, we
22 couldn't find Exhibit B. It was probably just -- I don't know
23 what the problem was. I'm not blaming it on anybody. But -- so
24 I don't really feel I've reviewed the doc -- I know I haven't
25 reviewed some of the documents, so I'm not really in a position

1 to say, hey, they're not trade secrets because I haven't
2 actually reviewed them. I'm not sure I'd know it even if I did.
3 But -- so I'm more willing to close the courtroom if it'd be
4 relatively limited number of times and on limited evidence. But
5 you'll -- so we'll just play it by ear, and you'll give me a
6 heads-up; okay?

7 What do you all have on your agenda?

8 MR. BOTTARO: Your Honor --

9 THE COURT: It's good practice. Just look for the
10 light.

11 MR. BOTTARO: I see. I thought the light was on.
12 There was a story in the paper this morning. I don't know if
13 you saw it.

14 THE COURT: Yeah, I saw that.

15 MR. BOTTARO: Would you address that with the jurors
16 because I --

17 THE COURT: Yeah, I will. Yep. Let me ask you this.
18 Did both sides have an opportunity to see the story?

19 MR. REIDY: (Nodded head.)

20 THE COURT: I saw it, but I just kind of skimmed it
21 real quickly. Is there anything in the st -- let me ask you
22 this. Is anybody going to be overly concerned about the fact --
23 actually I think you'll be surprised at how few people read the
24 newspaper. But if they read the story, is any -- is either
25 party taking a position that the mere reading of the story would

1 be enough to exclude someone from the jury?

2 MR. BOTTARO: Not on the plaintiff's side, Your Honor.

3 MR. REIDY: Nor on the defendant's side, Judge. I
4 think that if the Court just satisfies itself and us that the --
5 or I guess itself in this case that the juror --

6 THE COURT: Well, no, you too because you're
7 ultimately --

8 MR. REIDY: Yes. You'll obviously decide that. But I
9 think we'd be looking, Judge, just to make sure that, you know,
10 it didn't create any predisposition that's a problem.

11 THE COURT: Right.

12 MR. REIDY: That's all.

13 THE COURT: And that's what I'll look for. Great.
14 But no, I'll be glad to -- I'll be glad to raise that.

15 MR. BOTTARO: And, Judge, when you ask or when we
16 introduce ourselves and whom we practice with and witnesses that
17 may be called, do you then ask any follow-up on that?

18 THE COURT: Yeah, I'll ask who they know. And the way
19 I've got it set up is -- normally -- I was trying to cut down my
20 involvement so that the lawyers would have more time because I
21 really believe in lawyer-conducted voir dire. So I was just
22 going to kind of introduce the lawyers and then find out if
23 anybody knows anybody. And then we'll go beyond if they know
24 them how that might, if at all, affect. And I didn't really
25 have the witnesses in there. I thought I'd let the lawyers do

1 that when I turn it over to you all. You can go through who
2 your witnesses are and see if any of the jurors know them. I
3 mean, most -- it seems like a ton of the witnesses are
4 out-of-state experts. But stranger things have happened
5 actually.

6 MR. BOTTARO: Right.

7 THE COURT: So I actually wasn't going to address the
8 witnesses. I was going to leave that for the lawyers to do.

9 MR. BOTTARO: And as far as objections or challenges
10 for cause, do you prefer us to stand or remain seated or -- when
11 we address the Court?

12 THE COURT: I don't care.

13 MR. BOTTARO: Okay.

14 THE COURT: I think you can remain seated is fine.
15 But if you want to stand, that's fine. Doesn't make any
16 difference to me.

17 MS. GHEZZI: Judge, I have one question.

18 THE COURT: Yes.

19 MS. GHEZZI: Do you let them know maybe after they're
20 empanelled that sometimes people at the tables will leave the
21 room and come back?

22 THE COURT: Yeah. Thank you. I think what I'll
23 explain is that while you all can come and go the jurors and I
24 can't. But that's the rule. People in those tables, they get
25 to come and go. Sitting here and sitting there, we stay. But

1 no, that's very -- yeah. Of course, I'll explain that, and
2 thank you for raising that.

3 Anything -- are there other things we need to talk
4 about or . . .

5 And on the PowerPoint slides, I'm not going to read
6 every -- I'm not going to read every city that Jones Day has
7 offices in, but I don't think it's enough to just say do you
8 know the lawyer -- do you think you know anybody that works for
9 Jones Day because that might not -- so I've got the cities in
10 there. I'm not going to spend a whole lot of time on it. I'm
11 just going to say it's a large firm with a lot of offices. Here
12 are the cities they operate in, just leave it up there for --
13 you know, I'm not going to dwell on it and go through every
14 single city but . . .

15 MR. REIDY: We understand, Judge. And if it might be
16 consistent, I think Mr. Rathke's firm has offices in Huron,
17 Wisconsin, and New York City.

18 THE COURT: Oh, I didn't realize that.

19 MR. REIDY: So -- I believe I'm right on that. I
20 looked on their website.

21 MR. KING: Your Honor, we do have an office --

22 MR. REIDY: Their website lists those two offices.

23 MR. KING: We do have an office in New York City.
24 It's about as big as this table, but you're welcome to mention
25 that to the court.

1 THE COURT: Okay. Do you have an office anywhere
2 else?

3 MR. KING: In Hudson, Wisconsin.

4 THE COURT: Okay. I'll just go ahead and add that
5 physically to my PowerPoint. Thank you for pointing that out.

6 MR. BOTTARO: We don't have any offices in Dakota
7 Dunes or anything like that so . . .

8 THE COURT: Or North Sioux.

9 MR. BOTTARO: Or North Sioux, yeah.

10 THE COURT: Yeah, no tri-state.

11 MR. GRAY: Your Honor?

12 THE COURT: Yes.

13 MR. GRAY: I suppose -- and I'd forgotten it, but we
14 now have just opened an office in South Sioux City.

15 THE COURT: That -- okay.

16 I want to make sure I can pronounce the lawyers' names
17 correctly. And let me actually pull up that slide. So is it
18 Reidy or "ready" or something else? I'm sorry. You've said it
19 a number of times for me.

20 MR. REIDY: First guess was the correct one, Judge,
21 Reidy.

22 THE COURT: Reidy, thank you.

23 And Ghezzi?

24 MS. GHEZZI: Yes, Your Honor. Yes, Ghezzi. I always
25 like to say it's --

1 THE COURT: And, Gabriel, you're going -- Gabriel,
2 you're going to really have to help me out on yours so . . .

3 MR. SCANNAPIECO: My last name's pronounced
4 Scannapieco.

5 THE COURT: Scannapieco?

6 MR. SCANNAPIECO: Yes, Scannapieco.

7 THE COURT: Scannapieco.

8 MR. SCANNAPIECO: Yes.

9 THE COURT: Is that close enough, or is that -- I
10 don't want to get close. I want to try and get it.

11 MR. SCANNAPIECO: That's dead on.

12 THE COURT: Okay. Thank you.

13 And is Mr. Morrison sitting next to you? Yes. He's
14 the Abbott rep?

15 MR. MORRISON: Good morning, Your Honor. Yes.

16 THE COURT: Good morning. Welcome.

17 MR. MORRISON: Thank you.

18 THE COURT: Thank you. The two-week trial estimate,
19 it's so hard to estimate, particularly the longer the trial
20 the -- you know, it's pretty easy to estimate a two-day trial.
21 The longer you get out, very hard to estimate. And I'm not
22 super concerned even though I have a patent case that's
23 allegedly starting the day this ends, the next day that starts,
24 and I think we've scheduled it for -- is the 21st a federal
25 holiday? Yeah. So I think that's probably supposed to start on

1 Tuesday, the 22nd, although maybe we're starting on a federal
2 holiday because I often do. But you think we'll be done in two
3 weeks or not? I -- you know, it's an important case. I was
4 originally going to put you on a time clock. I don't think
5 I'm -- I'm not going to do that. But I mostly want to know what
6 to tell the jurors. I'm less concerned about the patent case
7 because they only have like six witnesses. So -- yes, Mr. Gray?

8 MR. GRAY: Your Honor, I think the holiday, wouldn't
9 that be Monday, the 20th?

10 THE COURT: Okay. The 20th?

11 MR. GRAY: Yeah.

12 THE COURT: Yeah, yeah. Thank you. So we're going to
13 start on the 21st I think. But this case could certainly
14 deliberate or we could have closing arguments on the holiday.
15 We're not going to take the holiday off if this case is still
16 going, but I assume you don't want this case to still be going
17 by then but . . .

18 MR. BOTTARO: We don't want it, but I think it's
19 probably wise just to say there's a potential that it could go
20 beyond two weeks.

21 THE COURT: That it could go into the third week,
22 particularly with deliberations.

23 MR. REIDY: I think that would be the safe course,
24 Judge, as well.

25 THE COURT: Okay. Thank you.

1 MS. GHEZZI: And Judge?

2 THE COURT: Yes.

3 MS. GHEZZI: This might be a good time to raise this.
4 We have one expert witness who is 71. His wife is about the
5 same age. She, he informed me recently, is handicapped, and she
6 can't travel alone. And he has to -- when we -- since August we
7 told all of our people we're going to be on the clock and this
8 is when we're going to go. And so we had said we're going to
9 put him on early in the case, and we thought we'd put him on
10 right at the beginning of the first -- of the second week. And
11 so he sort of arranged that with his wife.

12 And he has to travel like from Sioux City back to
13 Florida, pick her up and take her to Chicago because she cannot
14 travel alone. And so this is the only person we might have an
15 issue with in terms of seeking leave to take him out of turn if
16 he can go on Monday, the 13th.

17 THE COURT: Absolutely. Absolutely.

18 MS. GHEZZI: Okay. Okay. Thanks, Judge.

19 THE COURT: We'll take him whenever -- just give me a
20 heads-up like the day before.

21 MS. GHEZZI: Okay.

22 THE COURT: And we'll take him --

23 MS. GHEZZI: Thank you. We appreciate that, and he
24 will appreciate it.

25 THE COURT: Yeah, we do that all the time. Sure. Any

1 chance you want to call him by video so he doesn't have to
2 travel?

3 MS. GHEZZI: No, I don't think so.

4 THE COURT: Okay.

5 MS. GHEZZI: I think where he is, you know -- yeah.

6 THE COURT: Yep. You've got him scheduled, but
7 absolutely, we'll take him out of order.

8 MS. GHEZZI: Thank you.

9 THE COURT: And if it comes up for other witnesses
10 too, I know they're expensive to have sitting around, and so if
11 we need to take people out of order, we'll do it to accommodate
12 their schedules, so that's fine.

13 MS. GHEZZI: We do have one witness who probably will
14 be remote. But Gabe has worked it out so -- with your staff.

15 THE COURT: Okay. That's fine. Anything on the
16 plaintiff's agenda that we need to talk about?

17 MR. RATHKE: As the Court knows, we're going to read
18 some depositions. And my plan is to have people to my left play
19 all of the parts. I certainly was not going to ask Ms. Ghezzi
20 to read her part, but if she would like to, that would be fine
21 too.

22 MR. BOTTARO: We could certainly then read our parts
23 if they're doing the same thing with witnesses.

24 THE COURT: Do you have any desire to read your part?

25 MS. GHEZZI: No.

1 MR. REIDY: Zero.

2 MR. RATHKE: Okay. We'll have someone --

3 THE COURT: I like the definitive nature of the
4 statement. There's no ambiguity there.

5 MR. RATHKE: We'll have someone play Miss Ghezzi.

6 THE COURT: Okay. Anything else from the plaintiff?

7 Is there -- is there -- like are there lead
8 counsels --

9 MR. SCANNAPIECO: Your Honor?

10 THE COURT: -- that I -- if I don't know who to call
11 on I should be calling on?

12 MR. SCANNAPIECO: Excuse me, Your Honor. For purposes
13 of counter designations, should we be reading those in? Are
14 you -- at the same time?

15 MR. RATHKE: We'd be happy to read them in.

16 MR. BOTTARO: Well, but if they read theirs . . .

17 MR. REIDY: I think we'll just read -- if it's okay
18 with the plaintiffs, we'd just read the -- whoever's reading it
19 will read both the designations.

20 THE COURT: Will read both the designations and the
21 counter designations. Do you have any problem with that?

22 MR. RATHKE: No.

23 THE COURT: Okay. I think that makes the most sense.

24 MR. BOTTARO: As to your question, Your Honor,
25 Mr. Rathke is the lead counsel on the plaintiff's.

1 THE COURT: Okay.

2 MR. REIDY: Judge, I'm the oldest lawyer on our side,
3 so we'll use the oldest test.

4 THE COURT: Okay. Thank you. Any -- now let's go to
5 the defense. Anything on your agenda?

6 MR. REIDY: No, Judge, we don't have anything.

7 THE COURT: Okay. Thank you.

8 You know, it's awkward, but I need to bring it up.
9 This whole potential sanctions issue, you can look through my
10 record. I think you can count on less than one hand the number
11 of times I've sanctioned lawyers in 20 years. I was pretty
12 shocked when I read through the depositions, and just to make
13 sure my views weren't as idiosyncratic as they often are, I ran
14 it by another judge which I never do, Judge Strand, and he was
15 even more incensed than I was. And lawyers do that because
16 judges look the other way. And I'm not the type of judge that's
17 willing to look the other way. But I haven't given you in my
18 view sufficient notice. I mean, I just thought there were so
19 many obstructionist, frivolous objections that it was beyond
20 anything I have ever seen.

21 And, Mr. Rathke, both Judge Strand and I commented
22 that we don't know how you kept your patience with all that
23 nonsense that was going on because neither he nor I would have
24 put up with it either as a lawyer or as a judge.

25 So I think what I'll do is one -- at the end of the

1 day one of these days I'm going to give you some more specific
2 notice. I'll probably just pick out one deposition because the
3 conduct was, I thought, repeated often, but I -- on the other
4 hand -- well, and then we can hold a hearing maybe next week in
5 the evening and give you a chance to respond to it. It's just
6 not something I think I can overlook so . . .

7 But I do want to give you more notice, so we'll just
8 probably have a half-an-hour session one evening, and I'll go
9 through what I thought the problems were.

10 Okay. We'll see you at nine.

11 MR. BOTTARO: Judge, since we're starting at nine this
12 morning, when do you anticipate the mid-morning break?

13 THE COURT: The mid-morning break will be at 10:30.
14 That's usually when I take the break. It's a little earlier
15 than normal because people often have had coffee, and so their
16 bladders are -- try and be practical. Their bladders require an
17 earlier break.

18 Now, when we get -- you know, today we'll probably go
19 till 4:30 or so, quarter to 5, something like that. Then
20 tomorrow we go to the 8:30-to-2:30 schedule, and we'll be taking
21 the mid-morning breaks anywhere between 10 and 10:15 usually and
22 the afternoon break between noon and 12:15. And we'll probably
23 take a 25-minute break. And, you know, you can feel free to
24 have food brought in and eat right at counsel table if you want
25 to. And the jurors will have goodies downstairs in the jury

1 room.

2 MR. RATHKE: Since we're going to later in the
3 afternoon, will there be a lunch break?

4 THE COURT: Today?

5 MR. RATHKE: (Nodded head.)

6 THE COURT: Intravenous feeding tubes. You know, it's
7 kind of like on the airline when they ask you to check for the
8 flotation cushion. Just reach under your -- yep. You see it
9 there, the feeding tube?

10 MR. RATHKE: I got it.

11 THE COURT: Okay. No. We'll be taking an
12 hour-and-15-minute lunch break today.

13 MR. BOTTARO: I'm glad you clarified that. I thought
14 that was the catheter, so it's the feeding tube.

15 THE COURT: Oh, right.

16 MR. BOTTARO: Thank you, Judge.

17 THE COURT: Or the enema. Okay. We'll see you back
18 here at nine. Thank you.

19 MR. RATHKE: Thank you, Your Honor.

20 (Recess at 8:40 a.m.)

21 (The jury venire entered the courtroom.)

22 THE COURT: Good morning, everybody. How excited are
23 you to be here this morning? Awesome. If you'd raise your
24 right hand, I'm going to swear you all in.

25 (The jury venire was sworn.)

1 (Voir dire was reported but not transcribed.)

2 (The jury was sworn.)

3 THE COURT: Okay. Thank you. Please be seated.

4 Mr. Sun and Miss Ford, why don't we have you move to the back
5 because we just have two lonely jurors back there. And that way
6 that will give us four in the front row and four in the back
7 row. And then why don't you slide down so you can be in the
8 middle. Yeah, that's fine. It doesn't have to be -- I guess
9 there's no exact middle but -- Lisa, you want them to move down
10 one? Miss Kilberg, if you could move down one, that'd be great.

11 And notice there are cup holders. I'm proud of the
12 fact that we're the first federal courtroom in the United States
13 to have cup holders that I'm aware of, and I'm pretty sure I'm
14 right about that. And that came about as a result of a juror
15 quite a few years ago raising her hand in the middle of trial
16 and saying why do the lawyers have things to drink, why does the
17 witness have things to drink, why do I have things to drink and
18 we don't have any? So we changed that. So you can bring
19 anything you want into the courtroom as long as it's
20 nonalcoholic. We save the alcohol for the lawyers. But the
21 jurors, you know -- no, I'm just kidding. As long as it's
22 nonalcoholic.

23 So here's what we're going to do. We're going to be
24 in recess until 1:15. When you come back at 1:15, you will have
25 a set of jury instructions, and then it's my obligation under

1 the law to go through these with you which I will. And then
2 you'll also have a notebook and a pen because you're allowed to
3 take notes if you want to. I actually have an instruction on
4 note taking. You don't have to take notes. Nobody's going to
5 read your notes. But if you want to take notes, you can. And
6 sometimes I think it's easier to just take the notes right on
7 the jury instructions if you want to. But it's really totally
8 up to you whether or not you take notes or you don't take notes.

9 And I wanted to talk to you about the schedule. Today
10 we're going to go till about somewhere between 4:30 and quarter
11 to 5 if we can have maybe a natural break or are done with a
12 witness. But our schedule the rest of the week and next week, I
13 hope you'll find it to your liking.

14 When I first started as a federal district court judge
15 20 years ago, I had 2 pretty lengthy trials. Matter of fact, my
16 first trial was a patent trial. And I did a questionnaire for
17 the jurors to find out which -- so we went a couple of weeks
18 doing the traditional kind of 9-to-5 which we're doing today and
19 then what I call my alternative schedule where we go 8:30 to
20 2:30.

21 And so that's -- we're going to use the 8:30 to 2:30
22 the rest of this week for 2 primary reasons. Well, actually
23 there's more than that. There's really maybe three or four good
24 reasons.

25 Particularly in the winter when it gets dark early, I

1 like the jurors to be able to get home early. I find that more
2 people can serve on juries when they can get home particularly
3 if you have kids, so it works better. Jurors unanimously like
4 the 2:30-to-4:30 sch -- I'm sorry, the 8:30-to-2:30 schedule
5 better every time I survey jurors, so I know you like it better.
6 I actually don't like it, but it's really efficient, and I have
7 a bunch of things scheduled in the afternoons, criminal cases,
8 sent -- mostly sentencings. And while I'm sure the defendants
9 aren't that anxious to be sentenced, I'm anxious to get those
10 resolved and have those go on their way. And so that's another
11 reason but not the primary reason.

12 I also think it's better for the lawyers. Lawyers
13 work really hard getting ready for trial and really hard when
14 they're in trial. And so this way they don't have to stay up
15 quite as late at night. They can -- we have a lot of
16 out-of-Sioux City lawyers. They can call back to their offices,
17 deal with other client emergencies, and it just I think works
18 better for the lawyers because they're fresher.

19 And it's kind of like skiing for those of you who have
20 been downhill skiers. You know, about 70 percent of the
21 accidents in skiing happen after 3:00. And I've often said
22 during jury trials not much good happens after three. The
23 lawyers are tired. They get irritable. I'm always irritable,
24 but I get a little more irritable. And the jurors, it's just
25 hard to pay attention for that long. So I think you'll find the

1 8:30-to-2:30 schedule will work to your benefit certainly on the
2 back end. You know, you do have to get here a little bit
3 earlier on the front end.

4 And in terms of efficiency -- we've actually tracked
5 it with the transcript pages -- it's just as efficient going the
6 8:30-to-2:30 schedule as doing the longer schedule. You just
7 compact the time, but you're just more efficient.

8 So you obviously need breaks. We'll generally take a
9 break anywhere between 10 and 10:15, and that will be a
10 25-minute break, and then we'll take another one between noon
11 and 12:15 in the afternoon, so there will just be two breaks.
12 We should have snacks down there for you, but if you don't like
13 what we bring, there's a refrigerator and microwave, and you can
14 bring stuff if you need to eat.

15 Let's see. I'm just drawing a blank here.

16 Okay. Obviously one of the things I'm going to tell
17 you repeatedly during the trial is keep an open mind till you've
18 heard all of the evidence. It's very important that you do so,
19 and you can't discuss this case among yourselves. Don't let
20 anybody talk to you about the case. If they do, report it to
21 me. And once all the evidence is over and you hear the closing
22 arguments of the lawyers to summarize and interpret the evidence
23 for you, receive my final instruction and go down to the jury
24 room to deliberate, then you can talk about it as much as you
25 want to with each other.

1 So we will see you back here at 1:15. It's about five
2 minutes to noon now, and we'll start back at 1:15.

3 Here's what's going to happen this afternoon. I'll go
4 over the jury instructions with you, and then we'll hear the
5 opening statements of the lawyers. Opening statements are not
6 evidence, but they're an opportunity for the lawyers to
7 summarize what they think the evidence in the case will be. And
8 then hopefully we may get through a witness or two or at least
9 start with a witness.

10 And then we'll just go through all the plaintiff's
11 witnesses, then go through all of the defense witnesses, see if
12 the plaintiff has any what we call rebuttal witnesses and then
13 hear the closing arguments of the lawyers and you'll be able to
14 deliberate. But that's probably not going to be till the end of
15 next week at the very earliest.

16 So congratulations. That's one of the things I'm
17 going to tell you in the instructions. You've been selected to
18 serve the United States of America as federal jurors. It's a
19 very, very important duty.

20 Oh, yeah. There was one thing I did want to tell you.
21 At the end of the case when you're done with your deliberations
22 and hopefully you've been able to reach a unanimous verdict, you
23 know, one way or the other, I'm going to come down, and I'm
24 going to meet with you, and I'm going to try and answer any
25 questions that you might have. I've been doing this for 20

1 years. And I'm going to give you a questionnaire. And you're
2 going to get to -- you don't have to fill it out. We don't keep
3 you captive, but it's in an envelope, and you'll take it home.
4 And hopefully most of you or all of you will fill it out. And
5 you get to evaluate me as a trial judge, whether I've done a
6 good job, whether I've been fair to both sides. You get to
7 evaluate all of the lawyers in the case on a number of criteria.
8 And I take that very seriously.

9 We've made huge changes in how our court does business
10 based on the feedback we get from you. So it's very important
11 for us to get that feedback, and it's very important for the
12 lawyers because lawyers who try cases in federal court are very
13 dedicated to their craft, and they're always trying to improve
14 and get better. So honest feedback from you will be very
15 helpful to them. So hopefully you have that to look forward to
16 at the end of the trial.

17 So we do start -- I think you'll find we start pretty
18 promptly. And so if you could be back just a couple of minutes
19 early so we could start at 1:15, that would be great. Thank
20 you. We'll see you back at 1:15.

21 (The jury exited the courtroom.)

22 THE COURT: Thank you. Please be seated.

23 Anything we need to take up from the plaintiff?

24 MR. RATHKE: Do you want the jury questionnaires
25 returned? I'd be happy to do it. I don't want them.

1 THE COURT: Yeah, if you don't want them. We have
2 a -- recycling, so that'd be great. You can just give them to
3 Matt. If you keep them, you get to come back and try the patent
4 case.

5 Mr. Gray, I think I'm going to appoint you to be in
6 that case, you know. That will be your third one in a row.

7 MR. RATHKE: So how long do you think your
8 instructions will last?

9 THE COURT: Will last?

10 MR. RATHKE: Yeah.

11 THE COURT: In perpetuity.

12 MR. BOTTARO: Will take.

13 THE COURT: Right. About 45 minutes probably. That's
14 just a guess, but, you know, they're pretty lengthy. Or, you
15 know, instead of me doing it, we could have the lawyers mime
16 them. I'm real big on miming. So any volunteers from the
17 lawyers to mime?

18 Mr. King, you want to develop your forensic skills by
19 miming the jury instructions?

20 MR. KING: I'm rusty. I'm too rusty.

21 THE COURT: Okay. Mr. Bottaro?

22 MR. BOTTARO: I volunteer Ms. Ghezzi.

23 THE COURT: There you go. Oh, yeah, but you can't
24 volunteer the other side. That's the only thing so -- okay.
25 Anything else we need to take up? We'll see you back here at

1 1:15. Okay. Thank you.

2 (Lunch recess at 12:01 p.m.)

3 THE COURT: Do you know if the jurors are all ready?

4 CSO STECKELBERG: They're ready.

5 THE COURT: Okay. Just a second here. Okay. Ready
6 to have the jurors brought in?

7 MR. BOTTARO: Yes, Your Honor.

8 MR. RATHKE: Yes.

9 THE COURT: Okay.

10 (The jury entered the courtroom.)

11 THE COURT: Thank you. Please be seated.

12 Members of the jury, I just -- I haven't told you
13 this, but we did talk about a stretch break, and you've had some
14 stretch breaks, and I found that taking stretching breaks helps
15 everybody stay awake and pay attention.

16 So when we do get to the witnesses, we have a rule
17 called sequestration. It's Federal Rule of Evidence 615.
18 Sequestration's a fancy word meaning that witnesses who are
19 going to testify can't be in the courtroom to hear the other
20 witnesses' testimony, and I think you can figure out the reason
21 for that. We don't want witnesses to be influenced by what
22 other witnesses testify to. And there are some exceptions.

23 So, for example, each side gets to have a
24 representative, so the plaintiff has a representative from
25 Security National Bank, and Abbott has a representative from the

1 corporation. And they may or may not testify. But other folks
2 will be excluded once the opening statements and the trial
3 actually begins.

4 So because it takes a moment or two for a witness to
5 get off the witness box and leave and for a new one to come in,
6 for me to swear them in, that's always a good time to take a
7 stretch break. So I'll try and remind you for a while, but then
8 you'll get in the habit. As soon as a witness steps down, you
9 can automatically stand up and take a stretch break till that
10 other witness is in the courtroom, I swear that witness in, the
11 witness is seated. When the witness then is seated, then you
12 can be seated, and that way you get some extra stretch breaks
13 out of the deal.

14 So you should have on your chair the small phone book
15 size set of jury instructions. I'm just kidding you. They're
16 really not that long. And it says on it "Instructions to the
17 Jury," and then it has what we call the caption. Every case has
18 a caption. It's just the name of the case. It's a way that we
19 keep track of our cases. So this is in the United States
20 District Court for the Northern District of Iowa, Western
21 Division, and the plaintiff, Security National Bank, Plaintiff,
22 as Conservator for J.M.K., a minor child, Plaintiff, Abbott
23 Laboratories, Defendant, says instructions to the jury. And
24 then you'll see there's a table of contents. So at any time
25 throughout the trial you want to look up one of the instructions

1 or think about it or take notes on it, you'll have a table of
2 contents for you to do that.

3 And then you flip the page, and you notice we have 20
4 instructions, and then we have a verdict form. And a verdict
5 form is simply how you record your verdict. But we'll go over
6 that. So if you flip the next page, then it says number 1,
7 introduction. And that would be the start of the jury
8 instructions. I'm going to go over these with you.

9 (The Court read instructions numbers 1 through 19 in
10 open court.)

11 THE COURT: But I would like you to turn to the page
12 following 44. It's what we call the verdict form, and this is a
13 three-page document that you'll fill out after you've concluded
14 your deliberations and hopefully reached a unanimous verdict.
15 I'm not going to read the whole verdict form, but I just want to
16 kind of point out what it looks like because it's kind of a
17 snapshot actually of the whole case.

18 Question 1 -- Roman numeral 1, the conservator's
19 claims, step 1, verdicts, and it just gives you an opportunity
20 on who you rule for on the three claims, the conservator or
21 Abbott. Then if you found in favor of the conservator on the
22 warning claim, then you have an opportunity to check which of
23 the warnings apply.

24 And then step 2, if you found in favor of the
25 conservator on one or more of the claims, you again have an

1 opportunity to fill out each form of damages that you've been
2 instructed on. And then there's a place to total the
3 compensatory damages.

4 And then step 3 is if you found for the conservator on
5 either the design defect claim or the warning defect claim,
6 there's an opportunity to put down punitive damages.

7 And then section 2 would be Abbott's specific
8 defenses. And it's a question of whether or not they've proved
9 the state of the art specific defense and then whether or not
10 they've proved the intermediary specific defense, place for the
11 date, foreperson will sign it, and the rest of the jurors.

12 Just so you know, the final instruction I give you
13 just tells you that you need to elect one of you as the
14 foreperson so that person can speak for you here in court.

15 So why doesn't everybody take a stretch break.

16 Please be seated, members of the jury.

17 Mr. Rathke, are you ready to proceed with the opening
18 statement?

19 MR. RATHKE: I am, Your Honor.

20 THE COURT: Okay. Thank you.

21 MR. REIDY: Your Honor, could I have just a moment
22 with Mr. Rathke?

23 THE COURT: You may.

24 MR. REIDY: Your Honor, we had an expert witness in
25 the courtroom that should be excluded for the opening

1 statements.

2 THE COURT: Yeah. Wasn't that the understanding?

3 MR. RATHKE: I thought the understanding was from
4 testimony, but she'll be happy to.

5 One thing that Judge Bennett said this morning really
6 scared me. He said that we've got some really good lawyers
7 here, and I hope during the course of the trial that I'll live
8 up to his expectations and yours and present the evidence that
9 you need to decide the case in a fair manner.

10 This story actually begins in 2001 when several babies
11 in a Memphis hospital got meningitis, and some of them died.
12 They determined that the bacteria that caused the meningitis was
13 *E. sakazakii*. And they traced that bacteria to powdered infant
14 formula that the hospital was providing for those infants.

15 Because of that very sad incident, the FDA determined
16 that it would do a survey of all the manufacturing companies in
17 the United States, you know, taking random cans of powdered
18 infant formula and test them rigorously for *E. sakazakii*.
19 Twenty-eight percent of the cans that were tested from all of
20 the manufacturers contained some *E. sakazakii*.

21 There's a group called the International Formula
22 Council which represents the companies. It's a trade
23 association, and Abbott and the other companies are members.
24 And they became very concerned about possible regulation which
25 might occur due to this *E. sak* problem.

1 But the IFC recognized the reality, and we have some
2 of those internal documents that you'll see and read at least
3 part of it. They recognized the reality, and so to quote one of
4 the documents -- this is an IFC document -- under current FDA
5 testing procedures, it is anticipated that E. sak will
6 eventually be found in powdered infant formula made by all of
7 the infant formula manufacturers. They also said in another
8 memo although proactive measures may be taken to reduce the
9 level and frequency and incidents of E. sak in powdered infant
10 formula, total eradication of the microorganism from powdered
11 infant formula appears unfeasible due to the nature of food
12 powder manufacturing. And they also said in reporting on the
13 extent of the problem they're having the published literature
14 has reported that since 1988 about 10 percent of the powdered
15 infant formula tested positive for E. sakazakii.

16 So this is real. I'll bet you didn't know that. This
17 is real. Powdered infant formula contains this bacteria
18 E. sakazakii. The question is always how much, but it is there.
19 And that's what this case is about. This isn't a case about
20 power lines cause cancer, you know, junk science. This is
21 science. Powdered infant formula contains E. sak. E. sak harms
22 babies.

23 Now, Judge Bennett explained to you the reason why we
24 have the name of the case. The Security National Bank of Sioux
25 City has been kind enough to act as conservator and bring this

1 claim on behalf of Jeanine, Jeanine Kunkel. We've been
2 referring to her as J.F.K. or J.M.K. or something like that.
3 Jeanine is the way I will refer to her because that's her name,
4 and she's now five years old. She's severely disabled. She
5 cannot walk. She cannot talk, and she never will. She's fed
6 through a stomach tube and essentially frozen at the capacity of
7 a five-month-old baby and will never go beyond that.

8 Now, how did this happen? How could this happen?
9 Well, it happened because she got a horrible meningitis
10 infection when she was nine days old from the powdered infant
11 formula that she was fed which was contaminated with this
12 bacteria called E. sakazakii. Abbott made this powdered infant
13 formula. The name that it used for selling it is Similac which
14 is a term that they use for all their formula. And this was
15 called NeoSure.

16 NeoSure is a type of powdered infant formula that
17 Abbott markets for babies under the age of 12 years -- or 12
18 months old who were born prematurely, and they call it NeoSure.

19 The bank is bringing this lawsuit on Jeanine's behalf
20 for making this contaminated powdered infant formula, for
21 providing it to parents for babies who should not have been
22 exposed to a product that could be contaminated with E. sak and
23 for not warning parents and their doctors that powdered infant
24 formula could be contaminated so that they could make an
25 informed choice not to feed it to their babies who were so young

1 as to be susceptible to infection from E. sakazakii.

2 So what are you in for? Well, you're in for a biology
3 lesson from a medical doctor and four Ph.D.s, lots of documents,
4 not necessarily in order. You'll have a fair amount of prior
5 testimony read to you. Doesn't sound very exciting, but the
6 case is interesting. It involves bugs and babies.

7 Now, as we start this case, I can understand why you
8 might be skeptical. You're looking at me and saying, "What? I
9 never heard of this before. Why haven't I heard about this
10 before? Isn't infant formula safe? Why would Abbott put a
11 product on the market that could make babies sick?"

12 And I understand these feelings and the fact that many
13 people think there's too many lawsuits. What I would like you
14 to do is really listen to your common sense because that's what
15 this case really comes down to, kind of a common sense, common
16 sense for Abbott, common sense for the mom, common sense when
17 you're listening to the experts.

18 And I think when you do, there may be too many
19 frivolous lawsuits, but this ain't one of them.

20 There's some rules that companies that make powdered
21 infant formula have to -- have to follow. They've got a
22 responsibility to design a safe product. And by design, I mean
23 in the large term. Who is the product intended for? Should
24 this product, powdered infant formula, be designed for a baby
25 who's under the age of 28 days?

1 They've got a responsibility to manufacture a safe
2 product, and they agree that if their product contains E. sak
3 that's a bad thing. They don't intend to have E. sak in their
4 product. So they have a responsibility to manufacture a product
5 that's safe and is E. sak free.

6 And they've got a responsibility to warn of serious
7 risks so that doctors and parents can make an informed choice
8 about this: Should we feed this newborn powdered infant
9 formula, or should we instead feed this baby sterile,
10 commercially sterile, ready-to-feed liquid formula, two
11 products, which one should we -- we need enough information to
12 be able to make that choice.

13 Now, the characters -- let me introduce you to the
14 characters here, and things are going to come up just like magic
15 on this screen behind me I hope. That's just to show you what
16 the words look like. Enterobacter sakazakii. It will be
17 referred to a number of ways. E. sakazakii is a very proper
18 way. It has a nickname of E. sak. Sometimes it's referred to
19 as ES.

20 It was first identified by 1980 -- around 1980 by
21 Dr. Jim Farmer. You'll meet Dr. Farmer because he's one of our
22 expert witnesses. He named it after a friend of his named
23 Dr. Sakazakii and a fellow scientist. And yes, Dr. Sakazakii
24 was honored to have this bacteria named after him.

25 Now, all living things are members of families.

1 You've probably heard that term. The family -- no, go back.
2 The family is kind of hard to pronounce, but it's --
3 enterobacteriaceae is how it's pronounced. It's often referred
4 to as EB, and that's the family. It's got some cousins that you
5 may be more familiar with: E. coli, salmonella. It's not a
6 good family.

7 However, as if this wasn't complicated enough, they've
8 changed the name. Next slide. In 2008 as they learned more
9 about this bacteria, they reclassified it, and they now call it
10 cronobacter, and there are seven species in the group of
11 cronobacter, and they are C. sakazakii, and then there's six
12 more. And these are important distinctions to make.
13 C. sakazakii and E. sakazakii, however, we're all talking about
14 the same thing.

15 So that's the -- that's the bug. That's the villain,
16 and now I'll tell you about its ride. Its ride is powdered
17 infant formula -- or is infant formula, and there's three types
18 of formula. I don't know if you all know this, but just to make
19 sure everybody's on the same page, there's the ready-to-feed,
20 often abbreviated RTF, which is commercially sterile and liquid.
21 And that is sold in bottles, and at the hospital it is in
22 individual servings. And it's ready to feed to the infant.

23 The second is concentrates. I mention that just so
24 you know it exists. It's also commercially sterile. And it's
25 also liquid, but you do add water. It has nothing to do with

1 this case. It's just another type of formula.

2 And then the third is the powdered infant formula, and
3 it is not sterile. It is not sterile. Even though many people
4 assume that it is, it is not.

5 And then finally its destination, and these are some
6 terms that will be thrown around, but they all have a very
7 specific meaning. An infant is a baby less than 12 months old.
8 A neonate -- and that's a term that's going to be used from time
9 to time. A neonate is a -- set it back, Pat. Neonate is a baby
10 that's less than 28 days old. And I think the judge in his
11 instructions used the word newborn, and those terms newborn or
12 neonate are synonymous in this case. Newborns, neonates, less
13 than 28 days.

14 Then there's some special types of babies. There's
15 premature. The line is 37 months (sic). And this baby was born
16 at 37 months, so it's not premature but right on the line. And
17 then low birth weight. Low birth weight is a baby who weighs at
18 birth less than 2,500 grams or less than 5 1/2 pounds. Jeanine,
19 when she was born, was born at 37 weeks and weighed 4 pounds, 14
20 ounces, so she was a low-birth-weight -- low-birth-weight baby.
21 So those are the characters.

22 Now, I'm going to tell you a little bit about some of
23 the experts that are going to testify here on behalf of
24 plaintiff.

25 One that we're going to start I hope, you know,

1 tomorrow will be the second witness, is Dr. Scott Donnelly.
2 Dr. Scott Donnelly is a microbiologist who was employed by
3 Wyeth -- that's W-y-e-t-h -- for many years, for 23 years. And
4 beginning in 2001 when this Memphis outbreak took place, it was
5 his job to keep E. sak out of the powdered infant formula that
6 his company made.

7 He will explain to you how powdered infant formula is
8 made, I mean, kind of a broad overview, not all the details.
9 And he'll tell you that ingredients are all mixed into a liquid;
10 okay? So you got a liquid which has all the ingredients, and
11 then it's pasteurized, so all the bugs that are in this liquid
12 are dead. Then it's dried. The dryer is a six-foot -- it's a
13 huge building. It's six foot -- six stories tall, six stories
14 tall. And when it starts at the top, it's liquid; and when it's
15 at the bottom, it's powder. That's how they convert it. We are
16 now in what he will call the dry phase. That's where
17 contamination can occur. It's in the dry phase. The dry phase
18 starts with the dryer and ends with the packaging.

19 He will tell you that the only way that you can keep
20 E. sak out of your product is to keep your factory clean,
21 rigorously clean, particularly that portion where the powder is
22 in the dry phase. That's how you keep E. sak out of your
23 powdered infant formula.

24 And he will testify -- he'll tell you that Abbott's
25 procedure to control E. sak in its factory were deficient in

1 several respects. They wet cleaned and then they did not use a
2 sanitary -- the sanitizing risk -- rinse.

3 They also went around and tested various portions of
4 their factory to look for bacteria, particularly E. sak, and he
5 will explain to you that the factory testing -- and it will
6 often be referred to as the environmental testing, testing
7 within the factory -- was deficient in a number of respects.

8 He will also tell you that the finished product
9 testing was deficient and that both could give rise to false --
10 false negatives. A false negative is when the testing says
11 negative but that's not true.

12 The finished product -- when Abbott makes a batch of
13 powder like this NeoSure, it's a hundred and fifty -- over
14 150,000 pounds is made at one time. That's a batch. That's a
15 lot of powder. That's tons and tons of powder. And what they
16 test is about -- oh, it's a little less than two pounds. That's
17 what they test. And when -- if the test is negative, the
18 product goes out the door and on to the market.

19 And he will tell you that that test is deficient in a
20 number of respects, again leading to false positives -- or false
21 negatives.

22 He will also testify that when you find E. sak in your
23 factory it's a big deal or at least it ought to be, but it
24 wasn't in Abbott. You see, Abbott found E. sak inside its plant
25 the very day that the batch which was fed to Jeanine, the very

1 day that batch was manufactured. They found it in the dryer
2 area and specifically in two '////, drains. '//////////
3 '//////////
4 '/////////.

5 '//////////.
6 '//////////. That's what they test. They say it's a
7 good indicator. If it turns out it's negative, then they
8 don't -- that satisfies them. That actually is invalid.

9 But in this particular case when they were in the
10 '//// drain, they did get a positive, several positives, on
11 their // test.

12 What they do then is they say, okay, now we're going
13 to test for E. sak. We're going to actually look for the
14 organism that we need to find. And guess what. That was
15 positive too. They found and tested E. sak in their factory in
16 the '//// drain the same day that Jeanine's powder was dried.

17 Then they did something else. They took that -- you
18 know, the testing is kind of like you might remember chemistry
19 or biology where you put stuff into petri dishes and let them
20 grow. That really is -- that's how they do it. And they grew
21 88 colonies.

22 Well, they decided to send them for another test.

23 '//////////
24 '//////////
25 '//////////;

1 86 were not tested the second time. ///
2 /// looked at them, says they're negative, and so Abbott
3 said, okay, no problem here. That's what happened. The batch
4 was then released to the market.

5 Another microbiologist who's the specialist in this
6 testing named Catherine Donnelly will explain to you why the
7 first test where they found the positive E. sak is more
8 conclusive than the second test and how all of the cultures or
9 at least most of them should have been ///
10 tested and that the testing should have sent out bells and
11 whistles.

12 And both Dr. Donnellys -- and they are husband and
13 wife. Both Dr. Donnellys will tell you that if you get a
14 positive test for a bacteria you're looking for like E. sak, a
15 subsequent negative test does not wipe out the positive test.
16 You still have a positive test, and you have to deal with it.
17 It cannot be explained away by "we'll give it another test;
18 turns out negative; no problem." But that's what Abbott did
19 which brings us to Jeanine.

20 You see, the batch -- that batch made it all the way
21 here to Sioux City. Abbott put it in a gift bag. And when the
22 gift bag -- you know, as we've talked about a little this
23 morning, gift bag is when the mom is discharged from the
24 hospital after giving birth, they give a gift bag, and it's for
25 promotional purposes. It has, you know, literature and free

1 stuff from the company.

2 And what do you know? In this gift bag given to
3 Jeanine's mother was a can of powdered infant formula NeoSure
4 and later ended up being fed to Jeanine because this case is all
5 about Jeanine.

6 Jeanine, as I mentioned before, can't do anything.
7 She needs 24/7 care. She was born a healthy baby on April 14,
8 2008, in St. Luke's Hospital here in Sioux City. Her mother had
9 had a previous child who is -- who gave birth cesarean. And so
10 this was a scheduled hospital visit where it's scheduled, you
11 come in this day, and we will do the C-section.

12 Jeanine was a twin, a fact that was known, of course,
13 quite a bit before that, months earlier. And on April 14, Megan
14 Surber, the mom, gave birth to her twins, Jeanine and James,
15 Jeanine being small not because she was particularly premature
16 although she was on the edge; simply because she was a twin.
17 She was 4 pounds, 14 ounces. Her brother James was slightly
18 heavier. But it was over 9 pounds of baby.

19 Jeanine was never breastfed. Her mother tried to
20 breast-feed her baby, her firstborn, and was unable to do that.
21 So that was contemplated that she would be formula fed.

22 And at the hospital she received NeoSure. The doctor
23 felt that NeoSure was the appropriate type of formula because it
24 is for premature babies, babies that need a boost of nutrient,
25 and there's -- the doctor is absolutely right. NeoSure is

1 definitely the right product for a baby like Jeanine.

2 And so during the time that she was in the hospital
3 she received NeoSure ready-to-feed in the single service --
4 single serving containers. She was discharged with her mother
5 at three days. And that's when she -- her mother received the
6 gift bag. The gift bag contained, besides promotional material,
7 a bottle of ready-to-feed, so more ready-to-feed and a bottle of
8 powdered infant formula.

9 Jeanine was healthy for 10 days until April 24 when
10 she developed meningitis, E. sak meningitis. And no one
11 disputes that it's -- E. sak is the bacteria, you know, because
12 they did the culture from Jeanine's body. They looked at it,
13 identified it as E. sak. So no one questions that.

14 Our first witness will be Janine Jason, and she'll
15 start this afternoon, and she'll explain to you that E. sak is
16 pretty harmless to most humans. And humans where it's not
17 harmless are newborns who have no bacteria in their gut to begin
18 with and they don't have stomach acid and they really don't have
19 much of an immune system at birth. And it's especially harmful
20 to newborns who are premature or low birth weight or have
21 immune -- problems with their immune system. If E. sak gets
22 into their digestive tract, they have no defenses, no defenses.

23 The E. sak will -- it's -- the perfect environment for
24 E. sak to grow is a baby's gut, and that's where it goes to town
25 and eventually goes to their brain and literally takes out their

1 brain. It enters the -- but it enters the digestive system
2 through the mouth, through the mouth. It goes into the
3 digestive system, into the blood, into the brain.

4 And this isn't particularly controversial stuff. The
5 World Health Organization and the entire scientific community
6 agree -- and I'll read you a short statement in a 2004 WHO
7 report, WHO being the World Health Organization. Amongst
8 infants, those at greatest risk for E. sakazakii infection are
9 neonates, particularly preterm infants, low-birth-weight
10 infants, or immunocompromised infants. There's no one that
11 disagrees with that statement.

12 As I said, Jeanine was born April 14. The events 10
13 days later are particularly important, and we'll spend some time
14 on that. But from birth until the evening of April 23, she was
15 fed ready-to-feed, commercially sterile ready-to-feed. She got
16 some of the single servings from the hospital which she used up.
17 And then she took the bottle of ready-to-feed and used that up.
18 And on April 23 she had used all of that up and was now turning
19 to the can of powdered infant formula, NeoSure, that Abbott had
20 given her in a gift bag.

21 And the first feeding was at nine o'clock in the
22 evening. She had been fussy and crying a little earlier that
23 evening but nothing in particular, and you'll learn that in the
24 evenings that's when babies cry more than any other time of the
25 day.

1 She was fed at nine o'clock, went to sleep. At
2 midnight she woke her mother because she was hungry, had her
3 second bottle of powdered infant formula, and went to sleep. At
4 4 a.m., she woke up, had her third bottle of powdered infant
5 formula, and went to sleep.

6 Then on -- some time -- and nobody's really watching
7 the clock at this point. It's about maybe 6 a.m. on the morning
8 of April 24, and Jeanine is getting fussy again, and the mom
9 will describe that. Finally, you know, it's time for her
10 feeding. Her mom gives her her fourth bottle of powdered infant
11 formula, and this time Jeanine's not particularly interested and
12 doesn't finish it.

13 The mom checks her temperature, and she doesn't have a
14 fever. And so the day goes on. And as the day goes on,
15 Jeanine's condition worsens. She doesn't eat her subsequent
16 feedings. By the afternoon she's developed a fever. Megan
17 Surber takes her temperature and sees that she's feverish.
18 Megan calls the doctor. Doctor says bring her into the clinic.
19 The doctor meets her at the clinic and says let's take her right
20 to St. Luke's Hospital. And that's when she is admitted. The
21 diagnosis was neonatal E. sakazakii meningitis. She was two
22 days later airlifted to Children's Hospital in Omaha.

23 Dr. Jason will explain that Jeanine ate sufficient
24 powdered infant formula to consume enough E. sak to cause an
25 infection and that enough time had passed between her first

1 feeding and the onset of symptoms.

2 So how do we know the source of the E. sak was
3 powdered infant formula, because that's really the question
4 here? If it is, they're guilty, they're liable. If it's their
5 powder -- if it's their E. sak, they've got no defense.

6 Well, first of all, it's the only thing she ate that
7 wasn't sterile. Megan even boiled the water from her tap before
8 she mixed that water with the formula. Everything that Jeanine
9 Kunkel consumed prior to 9 p.m. on April 24 was sterile. The
10 powdered infant formula, not the water, but the powdered infant
11 formula was the first and only nonsterile thing that she
12 consumed before getting sick. And her mom followed all of the
13 instructions on the label and more. So that's one reason. It's
14 the only thing she ate.

15 Second, there's the association, the epidemiological
16 association, that everyone knows exists between E. sak and
17 powdered infant formula. And when I say everyone knows, you
18 didn't know it, a lot of people don't know it in the public, but
19 the industry knew it. The industry knew it, and you'll see a
20 lot of documents showing their knowledge of that fact.

21 The third is what I mentioned before, that their plant
22 was contaminated with E. sak the very day this batch went
23 through the dryer.

24 And then a fourth reason is this: Dr. Jason is not
25 only a medical doctor, but she's also an epidemiologist trained

1 by the Centers of Disease Control. And she studied the
2 approximately 100 cases that -- of E. sak infection in babies
3 and saw that 90 percent of them -- the records demonstrate that
4 90 percent of them and maybe more but 90 percent for sure were
5 fed powdered infant formula. And this establishes an
6 epidemiological link between powdered infant formula and E. sak.
7 And this and the other factors led her to the firm conclusion
8 that the source of E. sak infection was the powdered infant
9 formula.

10 Now, Abbott doesn't agree. That's why we're here.
11 Abbott says, well, our powdered infant formula's safe and poses
12 no risk to babies. That's what it says. And it will point out
13 to you that the CDC got ahold of the rest of the can that
14 Jeanine was feeding from and tested it for E. sak and did not
15 find any. The FDA went out and got 17 cans from that -- this
16 huge batch which Abbott had created and tested those for E. sak
17 and found none.

18 And the explanation for that is this, and this will
19 come out and really not be contested. E. sak clumps. It's not
20 uniform throughout a batch or even a can. It's here, and it's
21 not here. It's not spread evenly. The clumps are microscopic
22 and can't be seen by the naked eye. Remember it's pasturized
23 and then dried, and in the factory powdered infant formula will
24 become contaminated when it has contact with surfaces and
25 areas -- or the powdered infant formula will become contacted

1 (sic) when it has contact with E. sak in the surfaces or areas
2 that it's in.

3 And this has happened in other cases where the other
4 tests after the child gets ill turn out to be negative. And
5 scientists at the CDC agree. But that doesn't mean that the
6 powdered infant formula doesn't cause it. What it means in a
7 sense is that a baby ate the evidence.

8 Through its IFC, the industry resisted -- and you'll
9 see this -- all efforts to warn parents that powdered infant
10 formula is not sterile. Now, by 2008 the cans did say it was
11 not sterile in real fine print. So the industry eventually
12 voluntarily provided that information to parents. But they
13 continue to oppose informing parents that powdered infant
14 formula may contain E. sak. In other words, they say it's
15 sterile (sic), but they don't say what it -- what the problem
16 is. They don't say what the risk is. They say don't -- be sure
17 to follow our instructions in making it, but they don't explain
18 that there's a bacteria that may be present. And they don't
19 explain that this risk is greater for neonates and particularly
20 those neonates that are premature or low birth weight.

21 In fact, Abbott makes a formula just for them, a
22 powdered infant formula just for them. Nothing's wrong with
23 their making the ready-to-feed NeoSure. It's a fine product and
24 perfectly safe. Why they make it in powder is hard to explain.
25 Abbott -- but it continues to market powdered infant formula

1 even though it sells a perfectly safe alternative, the NeoSure
2 ready-to-feed.

3 Abbott's going to point the finger. Abbott says not
4 us, not us. It must be them, them, them, them. Abbott blames
5 and points the finger at the mom, the dad, the older half
6 brother, all the relatives or friends who might have held the
7 baby, the kitchen, the food in the refrigerator, the family dog,
8 the city water. They even point the finger at the doctor and
9 say, "Why didn't you tell the mom that our product is unsafe?"
10 Talk about corporate responsibility. And I haven't even
11 named -- you won't believe the long list of other things that
12 may have caused this.

13 Trouble is -- for Abbott is that there's no scientific
14 evidence, none, to support it. Iowa health authorities went to
15 the home and tested for E. sak in the kitchen and did not find
16 any. Moreover, not one single case has ever existed of E. sak
17 infection in babies in which there's been -- it has been proved
18 that the cause was anything other than powdered infant formula,
19 not one. And it makes no sense. If babies got E. sak infection
20 from everything under the sun, there'd be a lot more cases.
21 Babies would be dropping like flies.

22 James, the twin brother, stayed at the hospital for
23 ten days because of some unrelated health problems he had. He
24 came home on April 24, the same day that Jeanine went to the
25 hospital. Jeanine -- or James was in the same environment.

1 Same relatives were holding him, same dog.

2 But there's two things different about James. One is
3 by the time -- he got his gift bag too, of course. By the time
4 they had run out or were getting -- you know, they fed him the
5 ready-to-feed first and by the -- and while they were feeding
6 him the ready-to-feed, they found out -- you know, that's when
7 Jeanine got sick and was diagnosed and the family understood
8 that powdered infant formula is associated. They never fed
9 James powdered infant formula. He never got powdered infant
10 formula. So that's kind of its own little study. Jeanine got
11 powdered infant formula and developed an E. sak infection living
12 in the same house, same relatives. James did not get powdered
13 infant formula, got only the ready-to-feed. And guess what. He
14 never got sick.

15 And un -- and unfortunately, the FDA, even though they
16 went -- through the Iowa health authorities went to Megan's
17 house, they never went to Abbott, they never went -- said we
18 want to inspect your plant, we want to test your plant, we want
19 to see if we can find E. sak in your plant. That never
20 happened. They didn't even ask for records that would tell them
21 what kind of environmental testing results occurred during the
22 time that this batch was made. That was never done.

23 If they had, they'd have found out about the /////,
24 drains, but they never did find out about the /////, drains, so
25 no official cause was ever determined. And since it could not

1 be certain, nothing happened, there was no recall, and Megan has
2 a sick baby.

3 Although science demands certainty, in a civil lawsuit
4 and in actually most things in human affairs, absolute
5 certainty's pretty hard to find. And the law doesn't require
6 it. And keep in mind, you know, a bunch of lawyers have been up
7 here balancing scales. The question to you, for you will be is
8 it more true that the powdered infant formula was the source of
9 the E. sak than any other source or all the other sources put
10 together?

11 So we're at the beginning of the case, and I've
12 talked -- I'm probably close to 30 minutes. At the end of the
13 trial I'm going to ask you to reach the only true, logical
14 conclusion that Abbott's powdered infant formula was the source
15 and that we have proved it more likely than not. Thank you.

16 THE COURT: Members of the jury, it's 10 minutes to 3.
17 We'll be in recess until 3:15. Thank you. And then we'll come
18 back and hear the defense opening.

19 (The jury exited the courtroom.)

20 THE COURT: Anything we need to take up, counsel?

21 MR. REIDY: Nothing from us, Your Honor.

22 THE COURT: Okay. Thanks.

23 (Recess at 2:53 p.m.)

24 THE COURT: Ready to have the jurors brought in?

25 MR. RATHKE: Yes, Your Honor.

1 MR. REIDY: Yes, Your Honor.

2 (The jury entered the courtroom.)

3 THE COURT: Thank you. Please be seated.

4 Mr. Reidy, any time you're ready.

5 MR. REIDY: Thank you, Your Honor. Ladies and
6 gentlemen, I want to take up the circumstances described in 2001
7 in Mr. Rathke's opening just to clarify a few things as to what
8 the proof will show.

9 This is the Memphis Portagen outbreak of 2001. And in
10 that thing, even though it was not several meningitises -- it
11 was only one, and it was not some deaths; it was just one
12 death -- it was obviously a very serious incident, and there
13 were a number of children who were colonized with E. sak, and
14 so they -- and it was traced back to the powdered infant formula
15 there.

16 But I want to make sure that you understand that the
17 proof is going to show that with respect to that instant the
18 powdered infant formula, of course, was not Abbott's and also
19 that the proof will show with respect to the testing that he
20 talked about where he said 28 percent of subsequent testing,
21 they found it in 28 percent of powdered infant formula samples,
22 it was actually 23 percent which is not too important. But it
23 may be important that none of it was Abbott's, and all the
24 product was recalled from all the manufacturers who were found
25 to be positive in that study. And, of course, none of Abbott's

1 was recalled at that time.

2 This is not a case about whether or not powdered
3 infant formula manufactured by somebody else at some other time
4 has or can cause E. sak meningitis infections. It's a case
5 about whether or not this can of powdered infant formula that
6 Jeanine Kunkel had three servings from caused her meningitis
7 E. sak, and that's what the proof will be about.

8 We will talk to you about Abbott's state of the art
9 manufacturing plant, and we'll have a witness, Sharon Bottock,
10 the quality assurance manager from there, tell you about how it
11 works and how things are put together there and how Abbott works
12 to be sure that they have a methodology of both careful
13 manufacture and careful testing to make sure that they don't put
14 powdered infant formula on the streets or for sale that has
15 contamination by E. sak or, for that matter, contamination by a
16 number of other pathogens.

17 Pathogens are, of course -- you know, can be
18 salmonella. There can be other ones that you have to worry
19 about, so they have to worry about all those, although we'll be
20 talking about E. sak in this case.

21 And she'll tell you how Abbott is dedicated to
22 providing a safe environment for the manufacture of powdered
23 infant formula so that when it leaves Abbott's process it's been
24 both manufactured correctly and then even though manufactured to
25 the state of the art then tested to state of the art so that if

1 there is any E. sak in the powdered infant formula it is caught
2 before it gets out for publication or before use. And that will
3 be shown to you.

4 She'll describe the man -- the way it's manufactured,
5 and it's manufactured in what's called a closed system. Once it
6 enters the system, it's -- it basically is inside pipes and
7 tubes until it comes all the way down to the dryer. And so it
8 goes through that system all the way through. It's an extremely
9 hygienic system. There's all kinds of cleaning done. Cleaning
10 is done in place. The cleaning that's done is appropriate.
11 You'll hear experts take on various battles about that, but it's
12 a highly mechanized process. It's meant to minimize the amount
13 of individual contact with the powdered infant formula.

14 //////////////////////////////////////
15 //////////////////////////////////////
16 //////////////////////////////////////
17 //////////////////////////////////////,
18 and it's a highly mechanized, very state-of-the-art process done
19 in very clean places and even isolated from the rooms in which
20 it's in by and large so that it processes through in a tube. It
21 comes through wherever it is in whatever process it can be so
22 that it's kept as much as possible in a closed system.

23 I do need to talk about these presumptive positives in
24 the drain, and you'll hear about that in great detail. And
25 you'll see that there's just straight-up disagreement.

1 The first thing I want to make sure you understand
2 from the facts is that the drain is not in the dryer system
3 itself. It's in a room in which the dryer system passes
4 through. I described for you how the system is generally closed
5 with -- it passes through various rooms. There is a drain. And
6 Abbott conducts extensive environmental testing. They test all
7 kinds of things. They test things that are far, far away from
8 the production. They certainly test things that are outside of
9 this closed system. The idea is to really be on top of this
10 possibility of E. sak and to really test as much as you can.

11 So even though the likelihood that a drain in a floor
12 in a room with a system passing through it that is essentially
13 closed to the environment that it's in could contain something
14 so that they go down there and test it and take swabs in there,
15 they do that because they're dedicated to making sure that
16 E. sak doesn't have any chance to get into their stuff and, if
17 it gets in there, that their testing finds it. And that's why
18 they were down there swabbing this drain, not because it was
19 actually part of the system in which the powder comes in
20 contact. It's not.

21 With respect to the way that works is they do a test.
22 ///
23 /// And you'll hear about this.
24 And they do that. And that will give you information as to
25 whether or not it belongs to this family of cronobacters and

1 with respect to whether it belongs to that -- or the family of
2 these bacteria.

3 And with respect to whether it belongs to that, you
4 get a -- this looks at some of the DNA. //
5 //
6 // That's what it's looking for. If it finds
7 it, it registers a presumptive positive.

8 Abbott's procedure which follows what the FDA
9 recommends is they then have their -- that test is then
10 //
11 // because that's what the FDA recommends,
12 //
13 // And the // then does a much more
14 extensive look at the DNA, and it comes up with a conclusion as
15 to whether or not you're dealing with E. sak or not.

16 And with respect to the stuff that was down in the
17 drain inside the room with the system passing through it, it
18 determined that that stuff was not E. sak.

19 So the first sort of area of debate that you're
20 hearing about in this prediction by the lawyers as to what the
21 proof is is that even though we're only talking about something
22 in a drain environmentally tested not inside the system in which
23 the powder exists, that as to what was in that drain, this
24 // test // was clearly negative
25 for E. sak. So it was a bug, but it was not E. sak.

1 And on our part, our expert, Dr. Martin Wiedmann from
2 Cornell University, will explain to you how this presumptive
3 positive works, what it means, what the // testing
4 means, how it works, and why after the // testing is
5 done Abbott can conclusively conclude and state that it was not
6 E. sak even in the drain in the room through which the system of
7 manufacture processed.

8 The FDA conducts examinations of Abbott's
9 manufacturing plant every year. They come out and take a look
10 at it, make sure that it's up to snuff, and you'll hear about
11 that during the course of the proof. We'll have that talked
12 about as well.

13 And Abbott also has a third party who comes in, a
14 scientific group that comes in, and also inspects their
15 processes for safety and for quality and goes through
16 everything. They also go out to the plant at Casa Grande,
17 Arizona, which is where this can was manufactured, and they look
18 through everything there as well.

19 Abbott's very concerned that the products that come
20 out are healthy and safe and that they don't cause illness, that
21 they help people avoid illness. NeoSure is a product that's
22 meant to help premature and low-birth-weight babies do well and
23 get back to full weight. And so obviously they are extremely
24 concerned that it not contain a bacteria which can actually
25 cause great harm to the baby, and they work really hard to make

1 sure that doesn't happen, and you'll hear all about that.

2 The other part that I want to talk to you about, the
3 proof that you'll see, is the testing. And I want to talk about
4 the testing, particularly related to this batch, and that is the
5 batch from which the one can from which the three feedings that
6 were given to Jeanine Kunkel came from, and so it's produced in
7 a large batch. The batch probably -- you know, it's a
8 commercial size batch. But they have regularly s -- regularly
9 specified testing with respect to that.

10 So there's two -- two points of testing that I'll talk
11 to you about briefly. One is the regular testing that's meant
12 to make sure that no product gets out of Abbott's plant with
13 E. sak in it.

14 And the second part of the testing is the specific
15 testing that was done once Jeanine Kunkel was diagnosed as
16 having E. sak meningitis and it was known that she had consumed
17 some Abbott powdered infant formula. Then there was a bunch
18 more testing both by Abbott and other people, and we'll have a
19 lot of proof about that, and I'll summarize some of it, what I
20 predict you'll see right now.

21 So put up slide 2.

22 Now, you don't need to figure these documents out, and
23 we'll get it up in a second. I think the blackout might be on.
24 We'll get these -- you don't need to spend time looking at the
25 underlying documents here or trying to figure out what's in the

1 background. The point in this case is that Abbott has finished
2 product testing that it did on this batch.

3 Now, this batch actually has two numbers associated
4 with it. And you'll see that it has the RE00 number at the top
5 of the call-out there and the RE10 number at the bottom of the
6 call-out. And those two numbers are assigned to this single
7 production batch because some of this product was going to
8 Canada. And if they change it where there's going to be some to
9 Canada and some to the U.S., they take the one production batch,
10 and they give it two different batch numbers.

11 In this case that also resulted because of the
12 protocols that they follow. Once they change a batch number,
13 they have to put it through testing so that the normal testing
14 of ~~////////~~ was actually -- in this batch, this batch was tested
15 for ~~////////~~, so there was E. sak and other pathogen testing done
16 on ~~////////~~, twice the normal amount with respect to this
17 particular batch.

18 And in all the testing that was done preshipment, the
19 E. sak was negative as you see in those two call-outs.

20 Let's go to the next one. So then the next one -- and
21 Mr. Rathke made reference to this which is slide 3 -- I want to
22 make sure the right one's up. Apparently we're having some
23 technical difficulty. Later when I'm operating it you'll see
24 real technical difficulty.

25 Okay. Slide number 3. And again, you don't have to

1 look beyond the documents at this time because you'll get a
2 chance to see these documents in detail during some of the
3 testimony that occurs in the case. But this is the CDC testing
4 of the can, so the Center for Disease Control which is obviously
5 interested in outbreaks of disease such as if there could be an
6 E. sak outbreak because of a contaminated shipment of a
7 manufacturer's powdered infant formula, the Center for Disease
8 Control came out and took a look at the can. And, of course,
9 they tested it, and it was negative, and they did the testing
10 they felt was appropriate to figure out whether it was in there
11 or not.

12 In addition to that -- you can move to the next
13 slide -- the FDA came out, and they went to the hospital. The
14 hospital had gotten four cases of NeoSure. There's six cans in
15 a case. So the FDA pulled all the other cans that were in
16 there, and they tested 17 cans. 16 of those cans were -- came
17 off the line within 120 seconds or in the same 120-second period
18 I should say as the can manufactured that Jeanine Kunkel used.
19 So each one of these cans gets a minute put on it. It gets the
20 date, the hour, and the minute put on it as it comes through the
21 production line because if there is a problem, they want to be
22 able to identify where in the line there is a problem.

23 And in this case because the hospital shipment had
24 probably gone to the boxes together, 16 of the 17 cans came out
25 within the same 2-minute period as the can that Jeanine Kunkel

1 ate from. And so those were all tested by the FDA, and as you
2 know, the FDA is charged with responsibility for making sure
3 that there's no products on the market that are adulterated.
4 They have the power to make recalls. They looked at this can.
5 They looked at 16 of these cans, and they tested them, and there
6 was no sign of E. sak. It was also negative for that.

7 Next, please.

8 And the final specific test of this batch that I want
9 to talk to you about or an element of this batch is that as
10 Abbott makes a batch and ships all the cans associated with the
11 batch, they keep what's called a library sample, so they keep a
12 library sample from each batch.

13 And after they learned of the breakout -- or I'm
14 sorry, the breakout. After they learned that Jeanine Kunkel
15 indicated that she had E. sak meningitis and had ingested their
16 formula, they then went back to their library and tested it, and
17 as you see under the number 1 there, it also was negative.

18 So this is an excessive bit of testing, and it's
19 summarized in slide 6 where '//////', twice the usual amount of
20 the batch, are tested in Abbott, all of them negative. The CDC
21 you'll see in the proof tested the very can, and it was
22 negative. FDA tested 17 cans of formula, 16 of which came out
23 in the same 2-minute period as the Jeanine Kunkel can, and then
24 Abbott went back and tested its library batch. Every single one
25 of those was negative for E. sak.

1 In addition to that, because the FDA did not feel that
2 there was indication that the powdered infant formula was the
3 source of the infection, there was no recall. There was no
4 diminishment of the amount of the sales. So this batch contains
5 hundreds of -- 100 -- about 100,000 cans which, depending on the
6 size of the feedings, whether it's a 2-ounce feeding like
7 Jeanine Kunkel was getting at the time or up to a 6-ounce
8 feeding which might be -- it's between a million and four
9 million feedings. So none of those were recalled off the
10 market. Those feedings occurred out there, and there were no
11 other reports of E. sak meningitis from that entire batch.

12 Abbott in its testing also went back and did finished
13 product testing for three batches made before and after, three
14 batches before and after this batch was made just to make sure
15 that there wasn't some problem with the system, make doubly sure
16 that there wasn't a contamination. So they went back and tested
17 other batches.

18 Now, you'll see that the evidence is clear that the
19 FDA and the CDC are very vigilant since the 2001 outbreak where
20 the one meningitis death occurred and several other children
21 were found to be colonized in a single intensive care unit down
22 in Tennessee. The FDA and the CDC really jump on these things
23 whenever there's a report of E. sak meningitis and infant
24 formula's involved.

25 And so they were all over this, and the evidence will

1 show that FDA experts don't agree that it had to be the formula
2 which is what the plaintiff's experts are going to tell you, had
3 to be the formula, it's always the formula when it -- and then
4 it goes. And you'll see what the evidence is on that as it
5 comes in. I don't think that will hold up. But clearly the FDA
6 does not agree with that, and you'll see that evidence.

7 So Abbott's -- you know, other reasons why it's fair
8 that we think the proof will cause you to conclude and the
9 evidence will show you is that Abbott's never had a recall of a
10 PIF product for E. sak that reached the U.S. market. So it's
11 never had a product on the U.S. market with E. sak in it that it
12 had to recall, and E. sak has never been found in any sealed can
13 of Abbott's PIF on the U.S. market ever. So they've never found
14 it anywhere in a sealed can. I say sealed can because sometimes
15 if the can is open in the home and there's contamination there,
16 it can cross-contaminate if there's contamination inside the
17 home. In this case it didn't cross-contaminate into the can,
18 but it's never been found in a sealed can which is the way of
19 establishing whether it came from Abbott.

20 Now, I do need to talk about non-PIF sources of
21 E. sak, and I will talk about it. But what I want to make sure
22 I make clear is that I'm not doing and neither is Abbott doing
23 what was said in the opening of Mr. Rathke which is blaming
24 somebody else for this. This is not blame the mother or blame
25 anybody else.

1 It is very important from a scientific standpoint that
2 we do talk to you about what the evidence will show with respect
3 to where E. sak has been found, where it can be inside the home
4 so that you have an idea of what the various risks are of where
5 the E. sak came from in this case. So we're not trying to blame
6 anybody with respect to this. What we're trying to make clear
7 is that it wasn't Abbott's can that did it; and, therefore, the
8 question is, okay, are there other places it could have come
9 from. And so that's why we talk about these other sources.

10 So it does exist widely in the environment. You know,
11 some of the scientific literature talks about it being, you
12 know, essentially everywhere. It's been in soil, water,
13 vegetation, meats, poultry, cereal, spices just to name a few of
14 the foods. It's routinely found in home and hospital
15 environments. Sometimes it's found in sinks, on bottle
16 scrubbers, dust contents. It's not about just what the baby
17 eats. That's not what's the case because many things that the
18 baby eats also come into contact with the environment. Nipples
19 come in contact with the environment. Bottles in which the
20 formula's developed come in contact with the environment. The
21 baby him or herself comes in contact with the environment,
22 touching clothing, being touched by others, you know, being
23 around other people who are infected.

24 E. sak is not something that only comes from powdered
25 infant formula. E. sak infections occur in adults who clearly

1 are not eating powdered infant formula. E. sak occurs in
2 infants who have not been fed powdered infant formula. So not
3 every infant who has E. sak has -- or who -- has had powdered
4 infant formula. Lot of people who get E. sak infections don't
5 get meningitis because they're an adult, but E. sak infections
6 come in the environment, and that's be -- they don't get it from
7 powdered infant formula. They have to get it from all these
8 places.

9 In humans you can find E. sak in catheters, feeding
10 tubes, sputum. Pneumonia patients produce E. sak in some cases,
11 IV lines, stethoscopes, and there's more reported cases of
12 E. sak infection. You could encounter E. sak tomorrow. You
13 might not even get sick. You could encounter a colony. It
14 could enter your body. You might not get sick, just depending
15 on how it affected you because you're an adult and everything
16 else.

17 But of cases where people get sick and where they go
18 in and they find out what bacteria is specifically making them
19 sick as opposed to just giving them a broad-based antibiotic and
20 sending them home knowing it will probably kill whatever
21 bacteria it is, but where they actually define whatever it is,
22 there's many more adults who are identified as having E. sak
23 infections despite their lack of contact with powdered infant
24 formula than there are children.

25 So let's put up number 7 which is up there already.

1 And that's just a list of various sources in the literature
2 where it can be found. Has nothing to do with blaming anybody.

3 With respect to the home -- and again, no blame
4 associated with this -- there's a lot of areas in the home that
5 weren't tested, and so we put up the various areas in the home
6 and which ones were tested and which ones were not. Just go
7 ahead and put it up, fill it in.

8 So there was some limited testing done eight days
9 after Jeanine Kunkel went in the hospital. At the home they did
10 test the two areas next to the sink and the aerator in the sink,
11 but the many other areas in a home where you could actually have
12 E. sak occurring, not through any fault of anybody and not for
13 anybody to be blamed, you know, homes are not sterile no matter
14 what we do to them, no matter how clean we are. They're not
15 sterile. Sterile is a really tough standard. Not even
16 commercially sterile, they're not sterile at all. You know,
17 people track things in. Dogs and pets track things in. People
18 can also carry E. sak bacteria in their hands, their feet --
19 doesn't have to affect them -- their clothing. You know, quite
20 a few people had contact with Jeanine Kunkel at the hospital.
21 They had contact with her after she came home.

22 At the same time as Jeanine became ill at home, her
23 father was very ill. In fact, he went to the hospital on the
24 day after she was admitted, and he had been sick for some time
25 and sick with pneumonia. And so he went into the hospital at

1 the same time. And so there's illness in the home at the very
2 time.

3 The food we use isn't sterile. Refrigerators aren't
4 sterile. She was drinking out of ready-made formula that was
5 being kept in the refrigerator, a 32-ounce bottle. She was
6 drinking two ounces at a time, so there were bottles that were
7 around for periods of time, used, taken out, put on the
8 countertop, used, put back in. You know, there's all kinds of
9 possibility of cross-contamination.

10 Now, the CDC did test a couple of areas but -- and
11 they did not find E. sak in the home eight days after the test
12 was done. But it is important to note that there's -- just like
13 everybody's home, there's bacteria in the home. They have
14 several cultures, not E. sak, of bacteria that they list as too
15 numerous to count. They don't give a value to it because when
16 they test the home, obviously there's things that can be in the
17 home and probably would be in my home as well.

18 Now, Abbott's pediatric infectious disease expert,
19 Dr. Shulman, who's been head of the division of pediatric
20 infection dis -- infection and disease at Lurie Children's
21 Memorial Hospital and is the hospital epidemiologist, the guy
22 who's charged in the hospital of figuring out where any bugs
23 come from within the hospital, he'll testify that you don't have
24 to eat bacteria, that this concept that it only comes in through
25 the mouth which it might have and it could have come from

1 sources other than the powdered infant formula, but, in fact, it
2 could come into the body in numerous ways, through any of our
3 what's called mucosal openings which include obviously your
4 eyes, nose, mouth, and any opening you might have in the skin.
5 It can even be breathed. It can be aerosolized by vacuuming or
6 by somebody running a hose or a sharp -- fast water flow, and it
7 can come up into the air.

8 And as I say, infants who've not had any powdered
9 infant formula and adults who have had no powdered infant
10 formula get E. sak-based infections, and they get it from the
11 environment, so we know it is in the environment. It's simply
12 not the case that if a baby who's fed powdered infant formula
13 gets E. sak it has to have come from the powdered infant
14 formula.

15 There's another reason why the proof will show that
16 the -- none of the three feedings over about six and a half or
17 seven hours that Jeanine Kunkel had from a powdered infant
18 formula can caused her E. sak infection. And Dr. Shulman, the
19 fellow from Children's Hospital, Lurie Hospital, in Chicago will
20 testify that it takes time after bacteria enters any person,
21 even an infant, before it can cause symptoms and infection,
22 before it can cause infection enough to the point where there
23 are symptoms.

24 And in his expert medical opinion -- you'll hear him
25 say this -- the medical records in this case and includes the

1 statements of how the baby was doing made to the medical
2 personnel at the time the family brought the baby in, that the
3 medical records in this case will show that Jeanine Kunkel was
4 already showing symptoms of the meningitis infection that she
5 had at the time she received her first feeding from powdered
6 infant formula.

7 Remember as Mr. Rathke told you she came home on the
8 17th. She went back into the hospital on the 24th. During that
9 week she received feedings from liquid formula. Remember I've
10 described the -- sometimes I think she had some ready-to-feed
11 and then she had quart bottles, 32-ounce ready-to-feed which you
12 would use for 2-ounce feedings, put it back in the refrigerator,
13 do whatever one normally does with those things.

14 And what Dr. Shulman will tell you is how ever the
15 infection got into her, how ever it happened, it was already
16 manifesting system -- symptoms at the time that she received her
17 first feeding of powdered infant formula because she only gets
18 her first feeding of powdered infant formula on the night before
19 she goes into the hospital. He'll describe for you the medical
20 and biological reasons why given the progression of symptoms the
21 Abbott powdered infant formula which is just her last three
22 feedings couldn't have been the source of her meningitis
23 infection.

24 I'm going to talk briefly about the label because this
25 case features most importantly the question whether or not there

1 was E. sak in the powdered infant formula that she received
2 which caused her illness.

3 But put the label up if you would. Good.

4 And this will be discussed at length during the trial
5 because there is a specific warning claim. Most importantly as
6 you've already heard, it comes into play if and only if there
7 was E. sak in the powdered infant formula that she consumes.
8 Then you look at the label to see whether it's fairly warned for
9 or not.

10 But with respect to this, the most important thing to
11 note about this is that the label does say at the very top --
12 the first thing it says is that it's only to be used under the
13 supervision of a doctor. There's a couple of other places where
14 it says consult your doctor. It does say in that first
15 paragraph over on the left -- and I'm not asking you to find it,
16 but it does say that the product is not sterile, and then it
17 provides instructions for how to prepare the product.

18 In this case Dr. Beck who was the pediatrician who
19 Megan Surber was using for her daughter Jeanine did, in fact,
20 order or indicate that NeoSure should be used. And he didn't
21 specify whether it should be NeoSure powder or NeoSure liquid,
22 and I think the evidence will be he didn't care, he didn't
23 distinguish between the two as creating risk or more safety and
24 so that he ordered it and so that it was under his care that
25 that was ordered.

1 Now, the FDA regulates powdered infant formula labels.
2 And Abbott's label exceeds -- you know, meets or exceeds the
3 requirements that the FDA have for a label. They add some
4 things that the FDA doesn't even require for its label. And
5 you'll hear from warning experts about whether it makes sense to
6 have really dire warnings about things on labels if, in fact,
7 the risk is very, very small, et cetera. And so you'll hear all
8 about that.

9 But again, even with respect to the labeling claim, it
10 starts with was there E. sak in the powdered infant formula that
11 Jeanine received.

12 So we do have a couple of affirmative defenses that
13 we'll be talking to you about. And again, those two only --
14 they only come into play again if you find that there was
15 powdered infant formula, so we won't be spending a lot of
16 time on -- I'm sorry, if you find that there was E. sak in the
17 powdered infant formula that Abbott shipped, and so we won't be
18 spending a lot of time on that for sure, but you will hear about
19 it. And they basically are that the Abbott production facility
20 was state of the art, that it was a state of the art production
21 facility, that both the way they produced it, the way they
22 tested for it, and the design of the system was state of the
23 art, was the -- you know, as good as you can do with respect to
24 making it.

25 Now, you know, you can always test more, you can

1 always do more things, but state of the art has a certain
2 meaning. Some of you will be familiar with it. And Abbott's
3 plant was state of the art, and there will be expert testimony
4 to that effect.

5 And the other one is that there was a learned
6 intermediary in that Dr. Beck said go ahead and use NeoSure and
7 did not specify or care whether or not it was powdered or not,
8 and so he was well aware of the circumstance with respect to
9 the -- how children, if they consume anything that has E. sak in
10 it, can get an E. sak infection. He was well aware of that, and
11 yet he prescribed this. And so there's a learned intermediary
12 defense that you'll hear.

13 I'm not going to talk to you about the damages in the
14 case other than just ask you that during that part of the case
15 pay attention to it and, you know, take your eye to what's being
16 claimed there. I don't think we're going to get to that if I'm
17 right about what the proof shows as to whether or not there was
18 contamination in the powdered infant formula.

19 So when we finish the evidence -- and the evidence is
20 what matters -- the Court's told you that what Mr. Rathke and I
21 say here is nothing more than lawyers' predictions as to what
22 something might be, and that's certainly true. But when we're
23 done and the evidence is in, I'm going to come back here, and
24 I'm going to tell you that I think the evidence came in pretty
25 much the way I said it would, that the evidence, in fact, does

1 not establish in any way, shape, or form by a preponderance or
2 any other standard that there was E. sak bacteria in Abbott's
3 powdered infant formula that Jeanine Kunkel received. It will
4 not show that, and I'll come back and talk to you then and ask
5 you for a verdict for the defendant, Abbott. Thanks very much
6 for your attention.

7 THE COURT: Okay. Why doesn't everybody take a
8 stretch break, and then we'll start in with plaintiff's first
9 witness.

10 Mr. Rathke, ready to call your first witness?

11 MR. RATHKE: I am, Your Honor.

12 THE COURT: Okay. Who would that be?

13 MR. RATHKE: That would be Dr. Janine Jason.

14 THE COURT: Good afternoon. If you'd just raise your
15 right hand.

16 JANINE JASON, PLAINTIFF'S WITNESS, SWORN

17 THE COURT: Thank you. Please be seated. You can
18 adjust the chair and the microphones so you can speak directly
19 into them. And would you state your name, please, and spell
20 your last name.

21 THE WITNESS: Sure. Janine Jason, J-a-s-o-n.

22 THE COURT: Thank you.

23 Mr. Rathke?

24 DIRECT EXAMINATION

25 BY MR. RATHKE:

1 Q. Would you state your name again one more time into the
2 microphone.

3 A. Janine Jason.

4 Q. And how do you spell Janine?

5 A. J-a-n-i-n-e.

6 Q. And how do you spell Jason?

7 A. J-a-s-o-n.

8 Q. Where do you live?

9 A. South Carolina.

10 Q. And where in South Carolina?

11 A. Hilton Head.

12 Q. And you flew here to Hilton Head (sic) at our request to
13 testify?

14 A. Correct.

15 Q. What has been your involvement in this case?

16 A. You contacted my company, Jason and Jarvis Associates,
17 about getting expert consulting.

18 Q. What is Jason and Jarvis?

19 A. It's a two-person consulting company that my husband and I
20 started ten years ago when we left the U.S. Centers For Disease
21 Control in Atlanta.

22 Q. And what is your profession and the profession of your
23 business partner?

24 A. We're both pediatricians, and we're both epidemiologists.

25 Q. How much of your business in, oh, let's say the last two or

1 three years involves litigation, how much of your income?

2 A. Our income, I would guess -- he's our CFO, so he's better.
3 But I would think about maybe 25 percent.

4 Q. And who hired you to look at this case?

5 A. Your firm which is Lommen Abdo.

6 Q. What did we ask you to do?

7 A. You asked me to review material and see if I was able to
8 give an opinion on whether Jeanine Kunkel's infection,
9 cronobacter infection, was due to powdered infant formula that
10 was contaminated before it left the factory.

11 Q. How are you compensated for this task?

12 A. On an hourly basis.

13 Q. Does your compensation depend on the outcome of this case?

14 A. No.

15 Q. Have you ever testified in a courtroom like this before in
16 front of a jury?

17 A. No.

18 Q. Tell the jury your areas of expertise, your specific areas.

19 A. I am a pediatrician. I'm an immunologist. I'm an
20 infectious disease specialist. I am an epidemiologist. I have
21 a background in health communications and also in analyzing
22 complex study designs.

23 MR. RATHKE: Do you think this is loud enough?

24 THE COURT: Well, are the jurors able to hear the
25 witness?

1 JUROR FORD: She should be a little louder.

2 THE WITNESS: I tend to talk softly.

3 MR. RATHKE: Does it matter which mike?

4 THE COURT: No. And they're cranked up. Let me make
5 sure I've got them cranked up full tilt. They are.

6 THE WITNESS: I'll work hard.

7 MR. RATHKE: And if you're having trouble . . .

8 BY MR. RATHKE:

9 Q. Tell the jury about your education.

10 A. I got my undergraduate degree, my bachelor's, at the
11 University of Chicago with highest honors, went to Harvard
12 Medical School. Then I went and did my internship and residency
13 at the Children's Hospital of Los Angeles, did a clinical
14 immunology fellowship at Toronto Hospital For Sick Children, and
15 did -- and did the epidemiology fellowship program at CDC. It's
16 called the Epidemiology Intelligence Service, and I think it's
17 probably the best epidemiology training program in the world,
18 but I'm biased.

19 Q. Tell us if you will the date you graduated from Harvard
20 Medical School.

21 A. 1975.

22 Q. And then you've indicated some training and education after
23 that. Could you kind of give us when about those things
24 occurred.

25 A. From '76 to '77, those years I did my residency. The next

1 year was my fellowship. I then was on faculty at Yale doing
2 very basic immunology research for two years. And then in 1980
3 I left and went to CDC. I had wanted to do child health and was
4 getting too caught up in basic research. And so the next two
5 years I did the EIS program, and I stayed on at CDC after that
6 until 2003.

7 Q. So you were an employee of CDC when you did the
8 epidemiology training?

9 A. I was an officer in the U.S. Public Health Service assigned
10 to CDC.

11 Q. What does that mean to be an officer in the U.S. Health
12 Service?

13 A. It's a uniform service, and it's nonmilitary, but you have
14 a uniform, and it's very much like the military services.

15 Q. Tell the jury, please, about your career at the CDC.

16 A. I had a number of different positions at CDC. I did both
17 epidemiology and laboratory research. Most of it was with the
18 Center For Infectious Diseases. The research sometimes was
19 directly in the lab, sometimes was primarily epidemiology and
20 analyses. I supervised groups doing that work. For a short
21 spell I supervised a group that assessed the national AIDS media
22 campaign and developed research techniques for communications.
23 And I was involved in public health policy formation, prevention
24 activities, a good deal of teaching and lecturing.

25 Q. What are your years of employment with the CDC?

1 A. 1980 to 2003.

2 Q. Where were you located? Where was your office?

3 A. It's the only federal agency that's not in the DC area.

4 It's in Atlanta, Georgia.

5 Q. Have you covered your CDC years?

6 A. It's a lot of years. I think so, yes.

7 Q. All right. Now, 2003 you leave the CDC.

8 THE COURT: Did -- I don't recall that the witness --

9 MR. RATHKE: I --

10 THE COURT: Just a second. I wasn't finished. I
11 don't recall that the witness ever told the jury what the CDC
12 was.

13 THE WITNESS: That's important.

14 THE COURT: Or what the definition of epidemiology is.
15 So I know all the wizards in the courtroom know it, but, you
16 know, we select these folks, and it's helpful if you define the
17 terminology for them.

18 MR. RATHKE: Thank you, Your Honor.

19 THE WITNESS: Okay. CDC's full name -- and its name
20 has changed through the years. But its current name is the
21 Center -- now you've got me all nervous.

22 THE COURT: I have a tendency to do that to folks.

23 THE WITNESS: Oh, goodness. I'm going to move on to
24 the second part and come back when I'm less nervous.

25 THE COURT: That's fine.

1 THE WITNESS: Epidemiology is the science, the medical
2 science, of looking at diseases in populations and to come up
3 with ways to identify the causes of diseases and to prevent
4 their occurrence.

5 And CDC is the Center for Disease Control and
6 Prevention, but they've stuck with the CDC and left off the P
7 part.

8 BY MR. RATHKE:

9 Q. In addition to your CDC or as part of your CDC experience,
10 could you tell the jury about your clinical experience.

11 A. The longest time I've spent clinically is during those 23
12 years at CDC, I was also on faculty at Emory University School
13 of Medicine in the department of pediatric infectious diseases,
14 immunology and epidemiology. And in that capacity I did what's
15 called attending where you take turns supervising medical
16 students, residents, and fellows. You provide patient care.
17 You do one-on-one teaching as well as lecturing. And I did --
18 my focus in this were very sick children and how the immune
19 system responds to various insults and how to deal with that.

20 Q. And what are you currently doing since 2003 retirement?

21 A. Since then I work pro bono part time at a free clinic.

22 Q. Where is that located?

23 A. On Hilton Head.

24 Q. Have you been published?

25 A. I've published or coauthored or authored over a hundred

1 scientific peer-reviewed papers, chapters, and one book for
2 parents on parenting premature infants. That book was published
3 by two big U.S. publishing companies, and then a German
4 publisher published it in Germany.

5 THE COURT: And, doctor, would you mind defining for
6 us the Latin phrase pro bono?

7 THE WITNESS: Yeah, it's -- I don't charge. I've
8 never charged a patient.

9 BY MR. RATHKE:

10 Q. Do any of your publications relate to E. sak?

11 A. Yes. In 2011 and 2012 I did a series of analytic studies
12 looking at invasive cronobacter infection in children, and the
13 results of that were published in a journal called Pediatrics.
14 That's the peer-reviewed journal of the American Academy of
15 Pediatrics.

16 Q. What was the publication date?

17 A. It was, I believe, November of 2012.

18 Q. And generally what did you -- in a very general sense, what
19 was the publication about?

20 A. The -- well, what I did was I collected all available
21 information on any case of cronobacter that was in a pediatric
22 patient s -- from the beginning, the first reported case which
23 was 1958, through to the end of 2010 and to get the information,
24 I looked at everything ever published. I contacted the authors.
25 I went through CDC records, FDA records, legal documents,

1 reports in the literature, basically any source I could find.

2 I then separated off cases that I defined as being
3 invasive, and it was a definition that's consistent with the
4 literature. But the gist of it was to look at only significant
5 infections. I characterized those cases, and then I split off
6 the cases that occurred in previously healthy children and
7 analyzed those further.

8 In 2002 the FDA sent a letter out to healthcare
9 providers, and the letter cautioned them about using powdered
10 infant formula which I don't -- I can't talk as quickly as you
11 can. I call it PIF so I don't get tongue tied. It cautioned
12 healthcare providers to avoid using PIF in newborns who are in
13 newborn intensive care units or NICUs, and it was specifically
14 because of the problem of cronobacter.

15 Over the next couple of years that information
16 disseminated to the pediatric community. So my next analysis I
17 looked at cases that occurred before 2004, and I compared them
18 to ones that occurred after 2004 to see if there was any
19 temporal association between -- any temporal changes in the
20 characteristics of the cases that occurred before and after that
21 time period.

22 And then the third analysis looked at the relative
23 costs of ready-to-feed and powdered formulas.

24 Q. And we'll get into that a little bit later. But that was
25 what you were researching in your paper.

1 A. Correct.

2 Q. Now, did you review any materials that are specific to this
3 particular case?

4 A. I would say almost certainly, but if I did, it's not
5 identified in the document, and I'd have to go back and look
6 over my notes.

7 Q. Okay. Let me ask you to do this. Tell the jury what you
8 recall reviewing about this case.

9 A. For that manuscript?

10 Q. No, no, no, no, no, no. In connection with your engagement
11 as an expert.

12 A. Oh, my goodness. All right. Specifically for this case I
13 reviewed CDC records, FDA records, health department records, a
14 number of depositions of the family and of some Abbott
15 employees, the reports and the deposition of the Abbott experts.
16 I don't know if you mean specifically. I also did an updated
17 literature review to see what else had happened since I last did
18 one.

19 Q. Did you review any medical records?

20 A. Oh, yes. I reviewed the medical records of the -- of both
21 Jeanine, her brother, and her father and her mother.

22 Q. And did you read a number of depositions from family
23 members?

24 A. Yes, I read the depositions and the corrections to
25 depositions of the mother, the father, and the maternal

1 grandmother.

2 Q. Did you review any documents generated by Abbott or the
3 industry?

4 A. Yes. I reviewed a large number of documents that were
5 related to what's called the Infant Formula Council or IFC.
6 It's my understanding that that is an organization of different
7 formula manufacturers predominantly from North America.

8 Q. Could the name of that organization possibly be the
9 International Formula Council?

10 A. That is very possible.

11 Q. And in addition to the materials that are specific to this
12 case, did you also review some, you know, general literature on
13 the subject because of this case?

14 A. Because of -- well, yes. I mean, basically I looked to see
15 what was new since I had already looked at everything for the
16 manuscript.

17 Q. Do you believe that you reviewed sufficient material to
18 reach an opinion regarding the source and cause of Jeanine's
19 illness?

20 A. I do.

21 Q. And do you have an opinion regarding the source and cause
22 of Jeanine's illness to a reasonable degree of medical and
23 scientific certainty?

24 A. I do.

25 Q. And what is that opinion?

1 A. It's my opinion that it is -- that the truth is more likely
2 than not that Jeanine's invasive cronobacter infection was due
3 to a virulent cronobacter that was in her powdered formula
4 before it was sealed and left the factory.

5 Q. Why do you rule in powdered infant formula as a source?

6 A. I think I have a slide for this.

7 Q. You do.

8 A. It would be slide 7. Cronobacter is what's called an
9 enteric bacteria and in --

10 Q. Excuse me. Could you say that word a little bit --

11 A. Enteric?

12 Q. En --

13 A. En, enteric, e-n-t-e-r-i-c.

14 Q. All right. And you said it was an enteric bacteria, but
15 you need to tell us what that means.

16 A. I was about to.

17 Q. Okay. Sorry.

18 A. That word comes from the Greek word for intestines, and the
19 reason it's got that name is that is where an enteric bacteria
20 likes to live. It gets in through the mouth, tries to take up
21 residence in the intestines, and there it will divide. If it's
22 one that doesn't cause illness, it may actually help us digest
23 food. If it's one that causes illness, it will keep dividing.
24 Ideally our body will fight back and just get it out of there.
25 If you don't win the battle, it can get through the wall of the

1 intestines and go to the rest of the body.

2 So by definition this is a bacteria that gets in
3 through the food. Salmonella is an enteric bacteria. E. coli
4 is an enteric bacteria. Jeanine Kunkel was fed ready-to-feed
5 formulas at her birth hospital. Ready-to-feed formulas or RTF
6 are sterilized. The manufacturer pasteurizes them, and that
7 kills any bacteria that's in there. She did perfectly well on
8 that until she was sent home at three days of age.

9 Her mom continued to feed her ready-to-feed formula
10 for the next six days. And then at 9 p.m. on April 23, she gave
11 Jeanine her first feeding of powdered formula, namely NeoSure
12 22. Up until then Jeanine was doing fine. She was thriving.
13 Her powdered formula was literally the only nonsterile thing
14 Jeanine had been fed up until that time.

15 There is a body of research that goes back at least 30
16 years, incredibly elegant epidemiologic research that has shown
17 the relationship between powdered infant formulas and invasive
18 infection with cronobacter in infants. And by infants I mean
19 very young infants in the first two months of life.

20 The connection has been both looking at it through
21 straight epidemiologic techniques showing that those that have
22 received a certain formula became infected. Those that did not
23 didn't to a level of significance that's beyond the likelihood
24 of chance.

25 Some studies have in addition cultured the organism

1 and matched it to what's in the infants. But again and again
2 between outbreak investigations and what we call sporadic cases,
3 individual cases, the link is incredibly powerful. It is the
4 only thing that has ever been shown to cause this infection in
5 infants.

6 And lastly, on the day that Jeanine's product began
7 production in Abbott's Casa Grande plant, Abbott was doing
8 routine environmental monitoring for contamination. This is a
9 known contaminant in factories. It's endemic in factories. On
10 the day her product began to be produced, Abbott had two
11 positive cultures for enterobacter sakazakii which is what it
12 was called back then. It was in the very place where her
13 product was being produced.

14 Q. Abbott tested this product, this batch, before it left the
15 plant. And its testing was negative for E. sak. Why don't
16 those negative -- and you're aware of that; right?

17 A. I'm aware of that, yes.

18 Q. Why is it that that final product testing which was
19 negative for E. sak, why doesn't that rule out E. sak or the
20 powdered infant formula as the source of the E. sak?

21 THE WITNESS: Pat, could I have slide tw -- slide 8?

22 Q. Eight.

23 A. You like 1. That's the first one.

24 I am sure you're going to hear more about this from
25 other experts. I could go on and on, but there are people who

1 know more about factories than I do by far.

2 This is the percent of end product that was tested by
3 Abbott before it released the product to the market. They
4 tested '//////', of the product. Lots of powdered formula --
5 and I did not know this until I got more involved in this issue.
6 They are massive. One lot of PIF weighs over 150,000 pounds.

7 The nature of contamination with cronobacter is that
8 it's clumped. As far back as 2003 at an FDA meeting scientists
9 at that meeting were pointing out that this bacteria was unusual
10 in that it kept clumping. They had trouble working with it
11 because they couldn't get it to stop clumping so they could work
12 with it.

13 At that very same meeting an FDA staff person who has
14 through the years worked a lot on this topic commented that, of
15 course, the contamination is not homogeneous, that it happens in
16 the dry production point and it's from unintentional contam --
17 an area or a piece of equipment will be contaminated, and
18 inadvertently a clump of contamination will fall into the
19 product. So it's not spread out evenly throughout the product.
20 But the testing being done makes that assumption.

21 Nothing is a hundred percent even if the testing were
22 done according to the kind of contamination there is. But when
23 you have this clumped episodic contamination, this amount of
24 testing is simply not going to be able to pick it all up.

25 MR. RATHKE: You can take that off.

1 Q. After Jeanine became sick, the can from which she was fed
2 which had some powder in it eventually found its way to the CDC
3 in Atlanta where it was tested, and it was determined that there
4 was no E. sak or at least they didn't find any E. sak in that
5 opened can. Why don't those negative results, why don't those
6 rule out the powdered infant formula as a source of the -- of
7 C. sak?

8 A. I think the glib answer would be because she ate it. There
9 was f -- I should mention that Abbott's own results, if you look
10 through their records, show that end product testing doesn't
11 necessarily pick up all contamination. There have been times
12 where they've tested a lot using the routine end product
13 testing, found it to be negative, and then gone back for one
14 reason or another and found it to be positive.

15 A paper came out in 2011 where someone did a huge
16 amount of work looking at not an Abbott lot but a lot of
17 contaminated product that had been released to market. And it
18 showed what the FDA folks knew back in 2003. You would have one
19 area with enough clumping that it could, in fact, cause severe
20 disease while the rest of it was either only slightly
21 contaminated or perfectly fine. And the comment of that author
22 was that in a public health sense the implication was that some
23 poor infant could swallow that one or two clumps and you would
24 have a catastrophe for that one infant.

25 So that's a long way around to the glib answer that

1 you could have contamination in one small portion of a can and
2 the rest of that can could be perfectly fine.

3 MR. RATHKE: I would like to mark for evidence a paper
4 that has not been admitted and just display it to the witness
5 for purposes of laying foundation.

6 Pat? It's Exhibit 151.

7 THE COURT: Just tell me again what 151 is.

8 MR. RATHKE: 151 is an e-mail.

9 THE COURT: Oh, right. Go ahead.

10 MR. RATHKE: Should I --

11 THE COURT: Yep.

12 MR. RATHKE: -- lay foundation?

13 THE COURT: Exactly.

14 MR. RATHKE: All right. Go ahead. We want to show it
15 on this but not on the screen yet.

16 THE COURT: Let me explain to the jury what's going
17 on. Most of the -- I should have told you this at the
18 beginning. I've been meeting with the lawyers on and off for
19 weeks if not months about the exhibits. And one of the things I
20 told you in jury selection was that because we try a lot of
21 cases in our district we do things more efficiently than most
22 districts. So most of the exhibits are already in evidence.
23 We've resolved objections, if any, to them, and they're already
24 in evidence. There are a few that are not.

25 So in order to determine whether or not I should admit

1 the exhibit, they have to show it to the witness. Lawyers use
2 this phrase they have to lay a proper foundation for it. In
3 other words, can the witness testify to what it is that would
4 convince me that I should admit it, and that's what's happening
5 right now.

6 BY MR. RATHKE:

7 Q. Dr. Jason, I've put before you what's been marked as
8 Exhibit 151. Do you see that in front of you?

9 A. Yes, yes.

10 Q. And that -- generally what that is is an e-mail from Anna
11 Bowen identified as a CDC person to an individual named Seth
12 Levine. Is that correct?

13 A. Correct.

14 Q. What's the date of the e-mail?

15 A. I think it's October 26, 2007.

16 Q. Do you know who Anna Bowen is?

17 A. Yes.

18 Q. Would you tell the judge and the jury who Anna Bowen is.

19 A. She is a pediatrician and an epidemiologist at CDC. She
20 worked on enteric infections and has worked for at least eight
21 years on this particular bacteria. She has published at least
22 one review article and at least one chapter that I know of on
23 this topic.

24 Q. Does she know anything about E. sak?

25 A. I would say she's -- in terms of epidemiology, I don't

1 think there's anyone who knows more than she does.

2 Q. And in the e-mail she makes some comments about an
3 investigation that was going on in 2007. Is that correct?

4 A. Correct, yes.

5 Q. And that's not this case at all. This case had not even
6 occurred; correct?

7 A. Correct.

8 Q. Are there some similarities between the facts in this case
9 and the facts in the case that she was commenting about in her
10 e-mail? Just yes or no.

11 A. Yes.

12 Q. And do you agree with the sentiments that she expresses
13 about those similarities?

14 A. I do.

15 Q. And do they help -- are they part of the foundation for
16 your opinion?

17 A. Yes.

18 Q. Do you recognize this e-mail as a -- you know, I know you
19 were at the CDC. I don't know if they were doing e-mail then.
20 Probably were. Is this a CDC e-mail?

21 A. I'm not that old. Yes, yes, definitely an e-mail.

22 MR. RATHKE: All right. I'd ask that Exhibit 151 be
23 admitted as a relevant business record and foundation for her
24 opinion.

25 * * * *

1 (Exhibit 151 was offered.)

2 * * * *

3 MS. GHEZZI: Your Honor, our objection stands. It's
4 not -- I mean, business record is really not the point. I mean,
5 we don't have her to cross-examine, and it's a year before --
6 almost a year before the event in this case. Dr. Jason is not
7 listed on it. She's not a recipient. It's not addressed to
8 her.

9 THE COURT: Actually none of that makes any difference
10 under 703, but he hasn't laid the proper foundation under 703.
11 There's a magic question you need to ask, and you skirted around
12 it. So do you have your rules with you, or you actually come
13 into a federal court without the rules?

14 MR. RATHKE: We have the rules.

15 THE COURT: Well, you haven't asked the proper
16 question under 703.

17 MR. RATHKE: Oh, I thought I covered it. Maybe I
18 didn't.

19 BY MR. RATHKE:

20 Q. Is this something you relied upon when you reached your
21 conclusions?

22 A. I would have the same conclusion with or without this. I'm
23 not sure what you're asking.

24 Q. Is this a document that would be part of -- part of the --
25 that you would have reviewed in the process of reaching your

1 opinion?

2 A. Oh, yes, I did re -- I did see this, yes.

3 Q. And did you in some measure rely upon that, on this
4 document, in reaching your opinion?

5 A. I think any intelligent person would feel more secure in
6 their opinion if other intelligent people working in an area
7 agree.

8 Q. And this is in agreement with your opinion.

9 A. Correct.

10 THE COURT: You were warm but no cigar. Why don't you
11 go back and read the rule.

12 Q. Is this something that an expert in your field would rely
13 upon?

14 A. Yes.

15 THE COURT: You're getting closer. You don't have the
16 rules with you?

17 MR. RATHKE: I do but . . .

18 THE COURT: Well, open it up to Rule 703 and figure
19 out what you need to ask.

20 MR. RATHKE: Wrong book.

21 THE COURT: It's in there.

22 MR. RATHKE: This is the criminal rules.

23 THE COURT: It doesn't make any difference. It's in
24 the criminal rules too. It's the same rule of evidence for
25 criminal and civil cases. I know you don't do criminal work,

1 but same rules of evidence apply.

2 Members of the jury, you can stand and take a stretch
3 break.

4 I'll give you a hint. It's the eighth word of the
5 second sentence of the rule.

6 BY MR. RATHKE:

7 Q. Would experts in your field reasonably rely upon this type
8 of data in order to reach the conclusion that you've reached?

9 A. If it's from someone like this, yes.

10 THE COURT: So what are you looking at me for?

11 MR. RATHKE: Oh, I'm sorry.

12 THE COURT: You offering the exhibit?

13 MR. RATHKE: Yes.

14 THE COURT: I'm going to sustain the objection. I
15 mean, she's allowed to testify that she relied on it, but it's
16 not independently admissible as substantive evidence. She can
17 rely -- she's already testified that she relied on it in giving
18 her opinion, but her opinion would have been the same without
19 it, and that she can testify to under 703. The underlying
20 document itself is not admissible unless you meet all of the
21 foundation requirements, and you haven't done that.

22 MR. RATHKE: May I ask her to describe the contents of
23 the e-mail?

24 THE COURT: Sure. To the extent that she relied on
25 it, sure.

1 BY MR. RATHKE:

2 Q. Go ahead.

3 A. I'm not sure I understand.

4 Q. Did -- the subject that we're talking about is the
5 after-the-fact inspection of an open can which is negative for
6 E. sak. That's the scenario that was presented in the case that
7 involves what's been marked for identification as Exhibit 151;
8 correct?

9 A. I gather from this conversation, yes.

10 Q. And what was Dr. Bowen's comment with respect to the fact
11 that the open can tested negative for E. sak?

12 MS. GHEZZI: Your Honor, excuse me. I have to object
13 because he's asking her essentially to -- I think to read -- to
14 read the document.

15 THE COURT: I don't think he's asking her to do that
16 at all. It's overruled.

17 MS. GHEZZI: Okay.

18 THE COURT: She's entitled to read the document. She
19 relied on it.

20 MS. GHEZZI: No, she can read it. I mean read it out
21 loud which is publishing it to the jury.

22 THE COURT: Well, she can summarize what it is in the
23 document that she relied on.

24 MS. GHEZZI: Absolutely.

25 THE COURT: You're right. She can't just go ahead and

1 read it and get around my ruling that it's not admissible
2 independently as substantive evidence. So you can summarize
3 that portion of the document that you relied on in formulating
4 your opinion.

5 A. That a open can was tested and was found to be negative,
6 but Dr. Bowen indicates to the person at the health department
7 inquiring about the results and what they mean, her response was
8 that this unfortunately does not mean that the infant had not
9 received contaminated material from that can because
10 contamination is clumped, so the rest of the can could have been
11 negative and it still could have been the source of the
12 infection.

13 Q. Thank you. Abbott claims amongst other things that
14 Jeanine's home environment including the people that would be in
15 the home could be the source of her C. sak infection. Why do
16 you rule out those sources?

17 A. I think that this will come up again later. Cronobacter
18 does not infect a healthy human being. Many decades of clinical
19 samples of healthy people who are not hospitalized and not
20 infants, cronobacter never comes up. Cronobacter can what we
21 call colonize. It can for a while live in very sick
22 hospitalized people. Even this is very rare. We're talking
23 about around the world maybe a hundred a year or something. But
24 you can occasionally get a positive culture from a very ill
25 hospitalized person, usually elderly, virtually always someone

1 who's got some immune problem because they're just so sick in so
2 many ways. But it does not cause the kind of infection we see
3 in newborn infants.

4 The people that Jeanine came in contact with at home
5 were all younger and healthy people. These are not people who
6 are going to be carrying around cronobacter.

7 Even more striking is just in the last few years
8 there's been some work that even further supports that these
9 infections come from powdered formula. And in that -- in some
10 of these studies, what they did was look at the strain, the type
11 of cronobacter, and I think I'll explain this later. I have
12 some slides. But even -- for even the very elderly people, it
13 is not the same strain of cronobacter that infects infants. And
14 when I say infects infants, I mean invasive infection, the kind
15 of infection that leads to death and meningitis.

16 Q. Going on to another topic, would you tell the jury a little
17 bit more about this bacteria known as enterobacter sakazakii?

18 A. Sure. Actually I think its father is going to be here
19 later in the week. Could I have slide 1, the one that you keep
20 wanting to give me?

21 Enterobacter sakazakii was identified in 1980 by a
22 microbiologist named James Farmer who at the time was working at
23 CDC. And he characterized the bacteria, recognized its
24 similarities to other enterobacteriaceae, the group that
25 included salmonella and E. coli, and so he put it into the

1 family. And here we're talking about what you call taxonomy.
2 It doesn't change anything about the bacteria. It's just a
3 matter of deciding what family it lives in.

4 And enterobacteriaceae is what's called a genus. And
5 a genus is kind of like an extended family if you were to have a
6 huge family reunion. So he put it in the extended family of
7 enterobacteriaceae. And could I have the next slide?

8 In 2008 mainly because of this issue more and more --
9 we're not talking about a huge number of people, but there's
10 some very good labs now that are looking at cronobacter
11 infections, and in 2008 a number of people working very actively
12 identified so many different variations that they decided it was
13 time to give cronobacter its own family.

14 And so enterobacteriaceae sakazakii which is what
15 James Farmer had called it was given a new name. And the new
16 name was cronobacter. And that name was picked because Crono is
17 a Greek god who ate his own children. And they subdivided the
18 bacteria into seven different species. So species would be like
19 a real family, a father, mother, brother, sisters. So if I
20 could have that slide.

21 So what you have with cronobacter is -- I'm not sure
22 how you do this with -- behind you. I'm new to this. Usually I
23 can look at a slide -- okay. All right. What -- actually you
24 can put that down for one second. I want to show something. Do
25 you see my finger? You don't see anything, do you? Okay.

1 We're going to have to just kind of picture this.

2 You see seven different clusters there and then little
3 clusters, little circles around those clusters. The seven big
4 clusters are what we call species, so that would be like your
5 family, your brother's family, your sister's family.

6 The little clusters are clusters that are identified
7 because even within those families we're not alike.

8 The biggest cluster is *C. sakazakii*, and now you could
9 highlight that. That's big because the most disease comes from
10 *C. sakazakii*, so they have the most stored isolates. Isolates
11 are where you collect a sample, you store it so you can study
12 it.

13 So that's the biggest because that -- it causes the
14 most trouble.

15 What used to be called enterobacter sakazakii now is
16 called cronobacter sakazakii, and all of those are in this
17 family. The other families -- if you take that down, the other
18 fa -- the others, many of them, most of them don't do anything.
19 They don't get in the human body. They don't do anything to us.
20 If we ever meet one, it's just going to pass right on through
21 us. A few of them are the ones that can cause mild problems in
22 old people who are hospitalized and who have bigger problems to
23 deal with. But when it comes down to invasive infection in an
24 infant, those are -- almost universally with maybe one or two
25 rare cases, mild exceptions, those are all *C. sakazakii*.

1 Q. So what kind of people get cronobacter infections?

2 A. Okay. Well, as I've just said, if you are a infant less
3 than two months of age and unlucky enough to come -- and let me
4 take it even one step further. Within that group that says
5 C. sakazakii, there are not that many of those even that can
6 cause invasive infections. There is -- one of the labs doing
7 very interesting work now is trying to identify which of these
8 bacteria do cause very bad infections. And one lab has
9 identified a genetic sequence that they've called sequence type.
10 And they've put different isolates into different groups of
11 sequence types.

12 So, for instance, if you -- it would be like dividing
13 people up into the ones that have blond hair or black hair or
14 gray hair. And then they look back and say, all right, I've got
15 these into groups. Is there anything unique about these groups?

16 So let's say I've grouped everybody by hair color and
17 I look at the people with gray hair and I say, oh, they're all
18 old. Well, that's what they did with the strain type. They
19 typed out -- and those are the little circles you see. This
20 is -- that's the lab that made -- that identified all these
21 different groups.

22 Well, within those little groups, there is one that
23 they've numbered ST4. ST4 and its very close relatives are
24 virtually the only one that causes severe invasive meningitis in
25 very young infants. Most of the others don't do anything. A

1 few of the others cause either mild disease or they go along for
2 the ride with very sick, very old people.

3 So they have narrowed down the type of cronobacter
4 sakazakii that causes these very severe infections. And what
5 they have found is if they look at the isolates, they find that
6 isolate in two big groups: Very young infants with meningitis
7 and severe infection and powdered infant formula.

8 They find these other ones in other foods. It is in
9 foods. There are certain cronobacter in -- they like cereal.
10 They like spice. But those are not the ones that infect kids.
11 Those are generally -- if they're in powdered formula, they
12 don't cause any harm. So they have narrowed it down to a very
13 specific family, close, close family of cronobacter.

14 And if you could put -- I know I didn't tell you this,
15 but could you put up slide 57? I had a long time sitting
16 outside, and I saw a couple slides that would hopefully --

17 MS. GHEZZI: Your Honor, can I just -- I mean, it's a
18 narrative. I'm fine with that. But is there a -- was there a
19 question?

20 THE COURT: That's --

21 MS. GHEZZI: I mean --

22 THE COURT: Right. I get your point. It's --
23 objection's sustained. You don't have to make faces and roll
24 your eyes. You can just make your objection.

25 THE WITNESS: So should I stop?

1 THE COURT: No. I was talking to the defense lawyer.

2 You need to ask a question.

3 MR. RATHKE: All right.

4 BY MR. RATHKE:

5 Q. Why do they call it ST4? Could you be a little bit more
6 specific as to what an ST4 -- what that stands for and what that
7 means?

8 A. ST4, the only -- I think the only way it got to be ST4 is
9 that they happened to -- that may be the fourth one they
10 identified. It -- in and of itself the 4 doesn't mean anything.

11 Q. What's the sequence strain? What does that mean?

12 A. The sequence type?

13 Q. Yeah, the sequence --

14 A. That's the genetic area they were looking at. And I think
15 we'll get into this later because it's important in terms of who
16 gets infected and how and how much it takes to get infected.

17 But organisms that cause -- or bacteria that cause
18 very bad infections are called virulent bacteria. And
19 scientists look for what makes one virulent and another one not.
20 The people that are doing the ST4 work know that this sequence
21 is not what makes them virulent. They just know it's for some
22 reason linked to the bacteria that causes this problem, and
23 that's in terms of everything I've said is not important, but if
24 you were doing research on this topic and you wanted to know how
25 to stop the infection, it would be important.

1 Q. Okay. We've talked about the virulent factor of ST4. Are
2 there other virulent factor that -- factors involving
3 cronobacter sakazakii which can create more virulent results?
4 A. Yes. I don't think I will show you slide 57. You know
5 what? If I could have slide 12. There's a factor that's
6 very -- it's very pertinent to this case because one thing that
7 will come up -- two things that will come up is something called
8 incubation period. An incubation period is the time between
9 when the bacteria gets into the body and when the person becomes
10 symptomatic. That's the definition of incubation period.

11 And for this particular -- for the invasive
12 cronobacters, it can be for some strains very, very, very short.
13 The other issue is how much of a virulent bacteria can cause an
14 infection. It varies from bacteria to bacteria, from strain to
15 strain. But for some cronobacter, it can take a ridiculously
16 small amount to have an impact.

17 And this is another lab. So there's one group of labs
18 working on strain type. Another lab has worked on a protein on
19 the surface of some bacteria. And they've called it outer
20 membrane protein A or OmpA, and this is a true virulence factor.
21 And you'll see in a minute I'll explain why.

22 But what they did with this is they did an experiment
23 where they took bacteria that had OmpA on their surface and they
24 took bacteria that didn't have OmpA on their surface and they
25 reconstituted powdered formula and they put one or the other

1 into the powdered formula. And they put very tiny amounts.
2 We're talking about no more than a hundred cells to a thousand
3 cells so very, very -- something that you would easily have at
4 least that many in a clump of what can get into powdered infant
5 formula.

6 And what they found was -- and they put it into -- the
7 animal model for this infection is a newborn mouse. So they fed
8 it to newborn mice, and what they found was if they fed these
9 very tiny amounts of the bacteria that had OmpA on their
10 surface, within 6 hours it was in their brain. Within 12 hours,
11 the poor little mice were lying on their back with their feet up
12 in the air. They were not dead, but these were not healthy
13 mice. They were not looking good.

14 The mice that got the bacteria without the OmpA on the
15 surface were perfectly fine. They weren't infected at all.
16 They were just -- they were doing very, very well.

17 They then put OmpA on the surface of the bacteria that
18 didn't have it, and the mice got sick just like they did if it
19 was a bacteria that naturally had it. So that's what a true
20 virulence factor is. You know that OmpA is helping that
21 bacteria get where it doesn't belong.

22 And I think in terms of this case it also shows how
23 very little bacteria you need if it's a virulent bacteria to
24 cause a very severe infection and how quickly a very virulent
25 strain can divide in the intestines, get through the intestinal

1 wall, and cause severe infection.

2 THE COURT: Mr. Rathke, I think now would be a good
3 time to -- you're not going to finish your examination in the
4 next 30 seconds I take it.

5 MR. RATHKE: (Shook head.)

6 THE COURT: Okay. Members of the jury, that's going
7 to conclude the evidence for today. I just wanted to remind you
8 of a couple of things. We'll be using the 8:30-to-2:30 schedule
9 tomorrow, so we'd ask you to be here a couple of minutes early.
10 You don't have to come super early, but we can't start without
11 all eight. So we'd like you to be here a few minutes early
12 because I think you'll find that I tend to start on time.

13 It's very important to keep an open mind till you've
14 heard all of the evidence in the case, and that's going to be
15 some time down the road.

16 I brought my jumper cables, so if anybody has a hard
17 time starting your car, you come back to the courthouse, let the
18 court security officers know down at the front station, and
19 either they will take my cables or I will stick around until I'm
20 sure all of you have left because we don't want anybody to be
21 stranded. So thank you for paying careful attention. And we'll
22 see you tomorrow morning at 8:30. Thank you.

23 (The jury exited the courtroom.)

24 THE COURT: Please be seated. I expect the lawyers to
25 have the rules handy. I expect you to know the rules. You

1 shouldn't even have to open it up, but you ought to have them
2 handy in the event you don't know the rule.

3 Miss Ghezzi, you made a speaking objection. Here's
4 what you said. Your Honor, can I just -- I mean, it's a
5 narrative. I'm fine with that. Yeah, really? You're fine with
6 that, and that's why you're making the objection. And then you
7 go on to say -- let's see. I lost it here. I'm fine with that.
8 But was there a question?

9 Here's what I expect you to do: Objection, narrative.
10 That's all you have to say.

11 MS. GHEZZI: Okay.

12 THE COURT: And it was a narrative.

13 MS. GHEZZI: Okay.

14 THE COURT: And much of her testimony has been a
15 narrative, probably because she's not a professional expert
16 witness like I assume we're going to see later in the case.
17 Well, I don't know who's going to call them, but I'd be
18 surprised if we don't see some experts who make a good chunk of
19 their living from being paid to testify in court. You almost
20 always see those in products cases.

21 So you're going to need to explain to your witness
22 what it means to go on the narrative, and then you're going to
23 have to do a better job of asking a precise question so that she
24 can answer that question and not go off into what she thinks the
25 next three or four questions you're going to be answering are.

1 Just for Dr. Jason's benefit, a witness can only
2 answer the question asked, and they can't like go on and do
3 these long explanations. We call that a narrative. So -- and
4 it's not necessarily -- I'm not blaming anybody, but if the
5 lawyers ask a very precise question, you can answer that
6 question, then wait for the next question. And you should be
7 able to get everything you want to get out if they ask the right
8 questions. But that's up to the lawyers.

9 THE WITNESS: So if they ask something that would be
10 on a slide, am I allowed to show a slide?

11 THE COURT: Well, you're allowed to show the slides,
12 but you're not allowed to like keep changing gears and then talk
13 about this study and that study when he hasn't asked you about
14 this study or that study.

15 THE WITNESS: Oh, okay.

16 THE COURT: Yeah. So in other words, from your
17 perspective, you need to listen carefully to the question and
18 answer only the question that gets asked of you.

19 THE WITNESS: Does he have to ask about a specific
20 study?

21 THE COURT: Well, not necessarily. If he asks what's
22 your opinion about this and you rely on several studies, you can
23 talk about them. But you have to try and be responsive to the
24 question that he asks.

25 THE WITNESS: Okay.

1 THE COURT: And it just takes some practice so . . .
 2 Anything else we need to take up before we see
 3 everybody at 8:30?

4 MR. RATHKE: No, Your Honor.

5 THE COURT: Anything from the defense?

6 MR. REIDY: No, Your Honor.

7 THE COURT: Okay. We'll see you tomorrow morning.
 8 I'll meet with the lawyers. I'm here very early. If things
 9 arise and there's a problem, then I expect you to send me an
 10 e-mail, give me a heads-up, and be here early so we can take it
 11 up because at 8:30, I don't care if the earth is falling with
 12 regard to some problem you all perceive we're having, I'm
 13 bringing the jury in. If you haven't figured that out yet,
 14 that's the trick to getting along with me. I don't keep the
 15 jury waiting, period. And if you have some new instant
 16 emergency that you could have had at four o'clock in the morning
 17 and e-mailed me or come into the courthouse, that's your
 18 problem. It's not my problem. I'm not keeping the jury
 19 waiting, period. So we'll see you tomorrow.

20 (The foregoing trial was adjourned at 4:47 p.m.)

CERTIFICATE

21 I certify that the foregoing is a correct copy of the
 22 transcript originally filed with the Clerk of Court on 3-20-14
 23 incorporating redactions of personal identifiers and any other
 redactions ordered by the Court in accordance with
 Administrative Order 08-AO-0009-P.

24	<u>S/Shelly Semmler</u>	<u>4-29-14</u>
25	Shelly Semmler, RMR, CRR	Date

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